

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
14 February 2002 (14.02.2002)

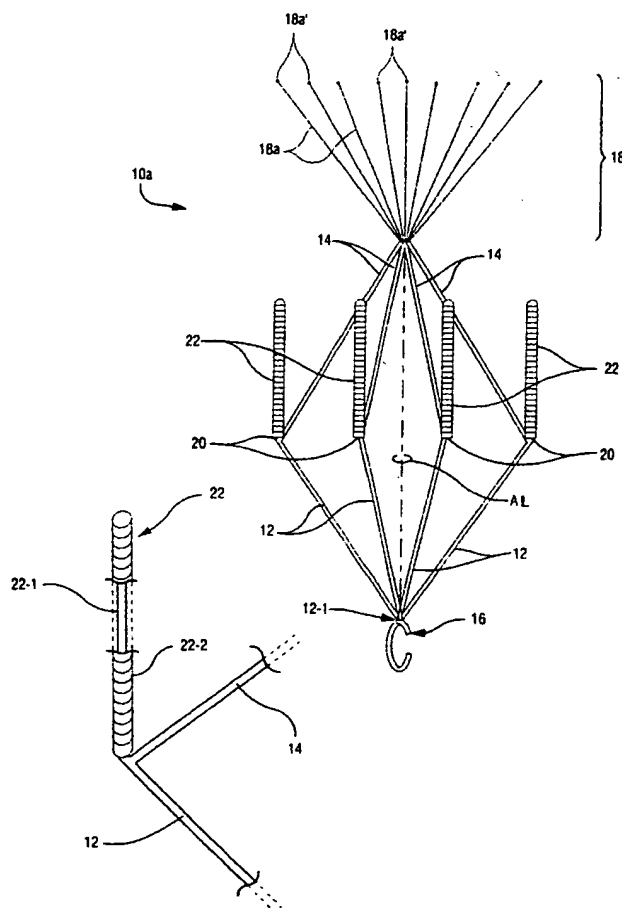
PCT

(10) International Publication Number  
**WO 02/11812 A1**

- (51) International Patent Classification<sup>7</sup>: **A61M 29/00**
- (21) International Application Number: **PCT/US01/23868**
- (22) International Filing Date: **30 July 2001 (30.07.2001)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:  
**60/223,190**      **4 August 2000 (04.08.2000)**      **US**
- (71) Applicant (for all designated States except US): **DUKE UNIVERSITY [US/US]; 230 North Building, Research Drive, Box 90083, Durham, NC 27708-0083 (US).**
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **THOMAS, John, [IN/US]; 9446 Chesapeake Drive, Brentwood, TN 37027 (US).**
- (74) Agent: **DAVIDSON, Bryan, H.; Nixon & Vanderhye P.C., 1100 North Glebe Road, Suite 800, Arlington, VA 22201-4714 (US).**
- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (84) Designated States (regional): **ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).**

[Continued on next page]

(54) Title: **TEMPORARY VASCULAR FILTERS AND METHODS**



(57) Abstract: Blood filters (10a, 10b) sized and configured to be positioned within a vascular vessel include a plurality of anchoring arms (22) having a removable sleeve (22-2) for temporarily anchoring the blood filter to a vessel wall. In especially preferred embodiments, the removable sleeve (22-2) is formed of a bioabsorbable material. When the filter (10a, 10b) is deployed, it is this removable sleeve (22-2) which comes into contact with the inner tissue wall of the patient's blood vessel (typically the inferior vena cava). When it is desired to remove the filter, endothelialization of the sleeve (22-2) has typically occurred but since the sleeves are a removable (separable) component part of the anchoring arms (22), the entire filter device (10a, 10b) can be retrieved thereby leaving the endothelialized sleeves (22-2) remaining in place on the interior wall of the patient's vascular vessel. However, such sleeves (22-2) will be absorbed over time (preferably by means of hydrolysis) since they are formed of a bioabsorbable polymeric material. In such a manner, the filters (10a, 10b) of the present invention allow relatively easy retrieval while minimizing (if not preventing entirely) harm to the vascular endothelium.

WO 02/11812 A1

**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

- 1 -

## **TEMPORARY VASCULAR FILTERS AND METHODS**

### **CROSS-REFERENCE TO RELATED APPLICATION**

This application is based on, and claims domestic priority benefits under 35 USC §119(e) from, U.S. Provisional Application Serial No. 60/223,190 filed on August 4, 2000, the entire content of which is expressly incorporated hereinto by reference.

### **FIELD OF THE INVENTION**

The present invention relates generally to the field of vascular filters, especially thrombus blood clot filters, and methods. More specifically, the present invention relates to temporary (removable) embolus blood clot filters and methods especially useful for placement in a patient's inferior vena cava (IVC).

### **BACKGROUND AND SUMMARY OF THE INVENTION**

Temporary immobilization and a number of medical procedures subject the patient to the risk of pulmonary embolism. This risk can be significantly reduced by the use of a filter implant. Currently available filter devices are not easily or safely removable after they have remained in place for more than approximately two weeks. The use of a permanent filter device would not be desirable when temporary protection against pulmonary embolism is needed, especially in younger patients. A temporary filter device that can be easily and safely removed after the threat of pulmonary embolism is over is most desirable.

- 2 -

Temporary blood clot filters are well known as evidenced from the following non-exhaustive list of prior publications and U.S. Patents (the entire content of each being expressly incorporated hereinto by reference): Hagspiel et al, "Inferior vena cava filters: An update", Applied Radiology, pp. 20-34 (November 1998); U.S. Patent No. 6,007,558; U.S. Patent No. 5,984,947; U.S. Patent No. 5,976,172; U.S. Patent No. 5,893,869; U.S. Patent No. 5,836,968; U.S. Patent No. 5,853,420; U.S. Patent No. 5,836,969; U.S. Patent No. 5,928,261; U.S. Patent No. 6,051,015; U.S. Patent No. 5,746,767; U.S. Patent No. 5,634,942; U.S. Patent No. 5,626,605; U.S. Patent No. 5,601,595; U.S. Patent No. 5,415,630 and U.S. Patent No. 5,383,887.

While a variety of proposals for removable blood clot filters exist in the art, improvements are still desired. For example, it would especially be desirable if a temporary blood filter could be implanted in a patient's inferior vena cava and remain therein for a reasonable time, yet be capable of withdrawal without causing damage to the vessel wall. It is towards fulfilling such a need that the present invention is directed.

Broadly, therefore, the present invention relates to a blood filter which is sized and configured to be positioned within a vascular vessel comprising a plurality of anchoring arms for temporarily anchoring the blood filter to a wall of the vascular vessel. Importantly, the anchoring arms include a removable sleeve. In especially preferred embodiments, the removable sleeve is formed of a bioabsorbable material. Thus, when the filter of the present invention is deployed, it is this removable sleeve which comes into contact with the inner tissue wall of the patient's blood vessel (typically the inferior vena cava). When it is desired to remove the filter, endothelialization of the sleeve has typically occurred but since the sleeves are a removable (separable) component part of the anchoring

- 3 -

arms, the entire filter device can be retrieved thereby leaving the endothelialized sleeves remaining in place on the interior wall of the patient's blood vessel. However, such sleeves will be absorbed over time (preferably by means of hydrolysis) since they are formed of a  
5 bioabsorbable polymeric material. In such a manner, the filters 10 of the present invention allow relatively easy retrieval while minimizing (if not preventing entirely) harm to the vascular endothelium.

These and other aspects and advantages will become more apparent after careful consideration is given to the following detailed  
10 description of the preferred exemplary embodiments thereof.

### **BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS**

Reference will hereinafter be made to the accompanying drawings, wherein like reference numerals throughout the various FIGURES denote like structural elements, and wherein;

15 FIGURES 1A and 1B are perspective views which depict particularly preferred embodiments of vascular filters in accordance with the present invention;

FIGURES 2A and 2B are enlarged perspective views of the anchoring arms that are employed in the vascular filters of FIGURES 1A  
20 and 1B, respectively;

FIGURES 3A-3F are enlarged perspective views which depict various exemplary structural configurations of the anchoring arms that may be employed in the vascular filters of the present invention;

- 4 -

FIGURES 4A-4F are enlarged perspective views which depict various exemplary structural embodiments of filter arms that may be employed in the vascular filters of the present invention;

FIGURE 5A is an elevational view of a delivery system that may be employed in accordance with the present invention, while FIGURE 5B is a longitudinal cross-section thereof;

FIGURES 6A-6H depict schematically a preferred sequence to deploy the vascular filters in accordance with the present invention;

FIGURES 7A-7D depict in an enlarged schematic fashion the manner in which the vascular filters may be deployed using the deployment sequence shown in FIGURES 6A-6H;

FIGURES 8A-8D depict in an enlarged schematic fashion the manner in which the vascular filters may be retrieved; and

FIGURES 9A-9D are greatly enlarged schematic cross-sectional views showing a representative anchor arm during the filter retrieval sequence.

#### **DETAILED DESCRIPTION OF THE INVENTION**

Preferred vascular filters 10a, 10b in accordance with the present invention are shown in accompanying FIGURES 1A and 1B, respectively, as including paired proximal and distal support arm portions 12, 14 which, in the expanded configuration shown in FIGURES 1A and 1B, radiate divergently from the elongate axis  $A_1$  of the filters 10a, 10b. The angle between these proximal and distal support arm portions 12, 14 is most preferably about  $135^\circ \pm$  when the filter 10a, 10b is in its expanded configuration. As will be discussed in greater detail below, a hook 16 is

- 5 -

provided at the proximal juncture 12-1 of the proximal support arm portions 12, 14.

5 The blood filter devices 10 of this invention are provided with a distal blood-filtering portion 18. More specifically, the distal juncture 14-1 of the distal support arm portions 14 is most preferably attached to the proximal end of a plurality of filter arms (a few of which are identified by reference numeral 18a in FIGURES 1A and 1B). These filter arms 18a thus radiate divergently away from the longitudinal axis  $A_l$  of the filters 10a, 10b, in the distal direction (that is, assume a generally conical configuration) and serve to trap or filter embolus blood clots from the patient's blood stream.

15 Importantly, the support arm portions 12, 13 are provided at their respective intermediate junctures 20 with a respective anchoring arm 22 so that the plurality of anchoring arms 22 are circumferentially spaced-apart from one another about the longitudinal axis  $A_l$  of the filters 10a, 10b. Specifically, as shown in FIGURES 1A and 1B, the anchoring arms 22 extend from the intermediate junctures of the proximal and distal support arm portions 12, 14, in a generally distal direction substantially parallel to the elongate axis  $A_l$  of the filters 10a, 10b. As shown in the embodiment of the filter 10a of FIGURE 1A, these anchoring arms 22 extend directly from the intermediate junctures 20 of the support arms 12, 14, whereas in the embodiment of FIGURE 1B, these anchoring arms 22 are provided with an extension arm section 24. The extension arm section 24 may be provided so as to facilitate easier removal of the filter 10b and minimize (if not prevent entirely) endothelialization of the support arm portions 12 and/14.

20

25

- 6 -

As is perhaps shown in FIGURES 2A and 2B, the anchoring arms 22 are most preferably formed by an inner anchoring arm 22-1 having a substantial longitudinal portion thereof covered by a removable sleeve 22-2. Since the removable sleeve 22-2 will remain in the patient's vascular tissue following retrieval of the device, it is important that the sleeve 22-2 be formed of a biologically compatible (biocompatible) material, such as for example, biocompatible metals such as stainless steel, titanium and nickel alloys (e.g., NITINOL<sup>®</sup> alloys), or biocompatible polymeric materials such as silicones, polyolefins, cellulose esters, biologically absorbable polymers and the like.

Advantageously, the sleeves 22-2 are formed for a biologically absorbable (bioabsorbable) material, most preferably a hydrolyzable surgical suture material. As shown in FIGURES 2A and 2B, the sleeve 22-2 may be formed by wrapping a bioabsorbable surgical suture monofilament around the periphery of the inner anchoring arm 22-1. The sleeve 22-2 may thus be removed as a unit from the inner anchoring arm 22-1, the purpose and function of which will be described in greater detail below.

Virtually any bioabsorbable polymeric material may be employed in the practice of the present invention to provide the removable sleeve 22-2. In this regard, the sleeve 22-2 may be formed of copolymers of glycolide with lactide or  $\epsilon$ -caprolactone comonomers may satisfactorily be employed. Such bioabsorbable copolymers are commercially available from the ETHICON division of Johnson & Johnson, Inc., Somerville, New Jersey, under the registered trademarks VICRYL<sup>®</sup> (a synthetic monofilament absorbable sterile suture material comprised of a copolymer of 90% glycolide and 10% L-lactide, coated with polyglactin 370 and calcium stearate) and MONOCRYL<sup>®</sup> (a monofilament absorbable sterile



- 7 -

suture material comprised of a copolymer of glycolide and  $\epsilon$ -caprolactone). Other monofilament suture material that may be employed includes bioabsorbable polyesters, such as poly(p-dioxanone), commercially available from the ETHICON division of Johnson & Johnson, Inc., Somerville, New Jersey, under the registered trademark PDS II®.

It is presently preferred that the bioabsorbable polymeric material be in the form of a monofilament which is wrapped around the inner anchoring arm 22-1 as shown in FIGURES 2A and 2B as such an embodiment is believed to be less traumatic on the vascular endothelium. However, if desired and/or if needed for a particular patient situation, the bioabsorbable material may be molded onto the inner anchoring arm as a monolithic removable coating. Furthermore, the inner anchoring arm may itself be structurally configured into a variety of ways. Possible exemplary forms of the anchoring arms are shown in accompanying FIGURES 3A-3F.

For example, in the embodiment shown in FIGURE 3A, the anchoring arm 22a is generally cylindrical in shape and includes a generally cylindrically shaped inner anchoring arm 22-1a which is coated with a generally cylindrically shaped removable tubular sleeve 22-2a formed of a molded bioabsorbable polymeric material. The external surface of the sleeve 22-2a may be smooth or serrated and the tip may be blunt or pointed as may be desired. In order to ensure removeability, a slight (but meaningful) space is provided between the inner anchoring arm 22-1a and the sleeve 22-2a so that these two structural components are in a relatively loose fitting relationship with one another. The shape of the sleeve 22-2a can be modified, however, to facilitate a relatively tight fit within the delivery system at the same time allow adequate contact with the vessel wall.

- 8 -

The embodiment shown in FIGURE 3B is similar to that in FIGURE 3A, except that the anchoring arm 22b includes an inner anchoring arm 22-1b having a substantially rectangular cross-section. The removable sleeve 22-2b thus also conformably has a substantially rectangular tubular cross-section and is formed of a molded bioabsorbable polymeric material.

In the embodiment depicted in FIGURE 3C, the inner anchoring arm 22-1c of the anchoring arm 22c is split longitudinally so as to form a pair of parallel fork arms 22-1c' and 22-1c", respectively. The molded sleeve 22-2c will thus have some of its material which occupies the spaced between the pair of fork arms 22-1c' and 22-1c" so as to provide increased traction to the sleeve, while yet still allowing for it to be removable during retrieval of the filter device 10.

Each of the inner anchoring arms 22-1d, 22-1e and 22-1f of anchoring arms 22d, 22e and 22f shown in FIGURES 3D-3F, respectively, are relatively shorter in length as compared to the anchoring arms depicted in FIGURES 3A-3C. Furthermore, it will be noted that each of the inner anchoring arm 22-1d and its molded removable sleeve 22-2d shown in FIGURE 3D has a pointed tip portion whereas the inner anchoring arm 22-1e and its molded removable sleeve 22-2e each has a rounded or blunt tip portion which may be desired in some situations as it will minimize injury to surrounding vascular tissue). The inner anchoring arm 22-1f of the anchoring arm 22f depicted in FIGURE 3F has a generally helical "corkscrew" configuration. The helical inner anchoring arm 22-1f is, however, likewise covered with a molded removable sleeve 22-2f of bioabsorbable polymeric material. Thus, the helical configuration of the inner arm 22-1f provides increased drag or traction with respect to the sleeve 22-2f. On retrieval of the device 10, however, since the relative

- 9 -

diameter of anchoring arm 22-1f is quite small, its helical configuration will yieldably straighten somewhat (i.e., in response to the force exerted on the device 10 during retrieval) to thereby allow it to be removed from its surrounding sleeve 22-2f.

5           As noted previously, the distal portion of the device 10 includes a blood filter portion formed of a distally divergent plurality of filter arms. The filter arms may be provided in accordance with the present invention as a number of structural and functional variations. For example, the filter arms 18a as shown in FIGURE 4A are the same as those shown in  
10       FIGURES 1A and 1B and terminate abruptly at respective terminal nodes (a few of which are identified as reference numeral 18a'). However, as shown in FIGURE 4B, the terminal ends of distally divergent arms 18b may be provided as inferiorly curved sections 18b'. FIGURES 4C and 4D are similar to one another in that the respective filter arms 18c and 18d  
15       thereof are formed as elongate loops which originate and terminate at the proximal juncture thereof. The filter arms 18d of FIGURE 4D, however, include a distal end portion 18d' which is curved inferiorly instead of terminating abruptly at a point as shown by the terminal ends 18c' in FIGURE 4C. Similarly the filter arms 18e, 18f as shown in FIGURES 4E  
20       and 4F include distal loop portions which may terminate abruptly at ends 18e' as shown in FIGURE 4E or may be inferiorly curved as in ends 18f' as in FIGURE 4F.

          The structural components of the filter devices of this invention can be constructed from virtually any biocompatible material. Thus, for  
25       example, stainless steel, tungsten, piano wire, super elastic memory wire, chromium alloys or any other elastic memory metal wires may be used. Most preferably, the structural components of the filter devices are formed of an alloy of titanium and nickel (e.g., NITINOL® alloys) due to its

- 10 -

5 advantageous thermal memory and biocompatibility properties. As noted previously, however, the removable sleeves of the anchoring arms are most preferably formed of a bioabsorbable material, although they may similarly be formed of other biocompatible materials, such as NITINOL® alloys, if desired.

10 Accompanying FIGURES 5A and 5B depict one particularly preferred delivery system 30 that may be employed to deliver the vascular filters 10 in accordance with the present invention. In this regard, the delivery system includes a delivery catheter 32 which is sized sufficiently so as to house therein the axially collapsed filter 10 (e.g., a size 7-8F catheter). A relatively stiff pusher catheter 34 (e.g., 5-6F catheter) is slideably received within the lumen of the delivery catheter 32 and serves to facilitate the pushing of the filter 10 beyond the distal tip of the delivery catheter 32 during deployment. An elongate conventional Gooseneck snare wire 36 extends through the pusher catheter 34 and includes a distal looped end 36a which is received within the proximal hook 16 of the filter 10. As shown in FIGURE 5B, the engagement between the looped end 36a of the wire 36 and the hook 16 of the filter device 10 is secured by sliding the pusher catheter 34 over the wire 36 and locking it in place by means of a clamp 38.

20 The distal ends of the delivery and pusher catheters 32, 34 are provided with respective catheter hubs 32a and 34a to allow independent manipulation of each such catheter 32, 34. An outer sheath 40 is provided of sufficient size (e.g., about 9F) to allow the delivery catheter 32 to be slideably inserted within its lumen. The outer sheath 40 is considerably shorter than the delivery catheter 32 so as to allow a distal end portion of the latter to extend beyond the distalmost tip of the former. However, the outer sheath 40 is of sufficient length to permit the delivery

- 11 -

catheter 32 to be positioned at the proper location within a patient's vascular system (e.g., beyond the confluence of the patient's iliac veins). The outer sheath 40 is provided with a proximal hub 40a. The 32a and hubs 40a may, if desired, be coupled one to another (e.g., by providing conventional Leur-type fittings) so as to enhance stability of the system  
5 30. A side arm 42 is provided in fluid communication with the lumen of the outer sheath 40 and includes a conventional stopcock 42a to allow introduction of saline solution as may be desired by the attending physician.

10 The system 30 is most preferably provided initially to the attending physician in a "preloaded" state as shown in FIGURES 5A and 5B. In such a state, an adequate distance is maintained between the hub 32a of the delivery catheter 32 and the hub 34a of the pusher catheter 34 by means of a spacer tube 44. The presence of the spacer tube 44 between  
15 the hubs 32a and 34a thereby prevents accidental deployment of the filter 10 during pre-surgical handling and/or shipping of the system 30. Just prior to use, therefore, the spacer tube 34 may be removed (e.g., by cracking the tube 44 if it is formed of a sufficiently brittle material, or unwrapping it if the tube 44 is formed of a more malleable material).  
20 Removal of the spacer tube 44 thus leaves the pusher catheter 34 free to slide within the delivery catheter 32 and thus allow the attending physician to deliver the filter 10 to the appropriate location within the patient's vascular system.

FIGURES 6A-6H sequentially depict in schematic fashion  
25 deployment of a vascular filter 10 using the delivery system 30 in accordance with the present invention, whereas FIGURES 7A-D schematically show in an enlarged manner the actual deployment of the filter 10 within the patient's inferior vena cava IVC.

- 12 -

A conventional Inferior Vena Cavogram is typically performed as part of the normal advance preparation for filter placement. Thereafter, referring specifically to FIGURES 6A and 6B, the patient's femoral vein FV may be accessed using the highly conventional Seldinger technique.

5 That is, a fine insertion needle IN is used to initially puncture the femoral vein FV as shown in FIGURE 6A. A guide wire GW is then threaded through the insertion needle IN within its lumen and manipulated until it is positioned in the inferior vena cava IVC (see FIGURE 6B). The needle may then be removed and serial dilators (one of which is designated by the reference identifier D in FIGURE 6C) may be threaded over the guide wire GW. The dilator D may then be replaced with a pre-loaded filter delivery system 30 as described previously so as to allow the filter 10 in accordance with the present invention to be deployed in a sequence to be described with reference to FIGURES 6D-6H.

15 More specifically, the outer sheath 40 may initially be threaded over the guide wire GW as a replacement for the dilator D (FIGURE 6D). The preloaded delivery and pusher sheaths 32, 34, respectively, separated by the spacer tube 44 may then be introduced through the lumen of the outer sheath 40 so that the distal tip of the delivery catheter 32 is positioned just above the level of the renal veins RV (see FIGURES 6E and 7A). At this time, the spacer tube 44 may be removed as shown by arrow A<sub>1</sub> in FIGURE 6F. The hub 34a of the pusher catheter 34 may then be positionally restrained by the physician while the hub 32a of the delivery catheter 32 is grasped and gently pulled back in the distal direction (as shown by arrow A<sub>2</sub> in FIGURES 6F and 7B). The filter 10, and particularly the distal filter arm portion 18 thereof, will therefore responsively begin to expand as the delivery catheter 32 is withdrawn within the lumen of the outer sheath 40. The pusher catheter 34 may be used to control the final

- 13 -

deployed position of the filter 10 by allowing the filter 10 to be pushed or pulled as desired by the physician within the inferior vena cava IVC (see FIGURES 6G and 7C). Once the filter 10 is completely deployed, the clamp 38 may be removed and the pusher catheter 34 gently withdrawn.

5 The Gooseneck snare wire 36 is then disengaged from the proximal hook 16 of the filter 10 and the whole retrieval system 30 withdrawn from the vascular lumen (see FIGURES 6H and 7D). Gentle pressure may then be applied on the groin at the site of access, to achieve hemostasis.

Accompanying FIGURES 8A-8D sequentially show in an enlarged  
10 manner, the sequence for retrieving the vascular filter 10 in accordance with the present invention. Similar to deployment described above with reference to FIGURES 6A-6H and 7A-7D, a retrieval catheter system essentially identical to the delivery system 30 described previously but without the pre-loaded filter therein may be positioned using the Seldinger  
15 technique. That is, after dilation, an outer sheath 40 may be introduced through which a delivery and pusher catheter 32, 34 are introduced to the site of the filter along with a Gooseneck snare wire 36. The looped end 36a of the wire 36 may then be connected to the proximal hook 16 of the filter 10 as shown in FIGURE 8A. The filter 10 is then gently withdrawn  
20 into the catheter 32 which serves as a housing for the filter during retrieval. If endothelization has taken place by the time the filter 10 is retrieved, the outer sleeves 22-2 removably covering the inner anchoring arms 22-1 will be retained within the vessel wall as the proximal support arms 12 begin to be pulled gently into the distal end of catheter 32  
25 causing the entire filter 10 to be collapsed onto its elongate axis A<sub>1</sub> (FIGURE 8B). The filter 10 in the catheter 32 can then be withdrawn into the outer sheath 40 and the whole system may then withdrawn from the vessel lumen (FIGURE 8D) leaving the endothelized outer sleeves 22-2

- 14 -

behind. As described previously, the outer sleeves 22-2 will be hydrolyzed and absorbed over time since it is made of a bioabsorbable polymeric material.

FIGURES 9A-9D 9D are greatly enlarged schematic cross-sectional views showing a representative anchor arm 22 during the filter retrieval sequence. As shown in FIGURE 9A, the exemplary anchoring arm 22 comprised of an inner arm 22-1 and a removable outer sleeve 22-2 formed of a bioabsorbable polymeric material may be positioned within a patient's inferior vena cava IVC as has been previously described. Over time, endothelization of the anchoring arm will typically occur as shown in FIGURE 9B by the endothelial tissue ET. Upon retrieval, the outer sleeve 22-2 will therefore remain positionally fixed to the vessel wall by virtue of such endothelization while the inner anchoring arm 22-1 is withdrawn therefrom in the direction of arrow A<sub>3</sub> in FIGURE 9C. The outer sleeve 22-2 will thus remain behind in the vessel wall as shown in FIGURE 9D following removal of the other structural components associated with the filter 10. However, since the sleeve 22-2 is formed of a bioabsorbable polymeric material, it will eventually disappear over time. In such a manner, the filters 10 of the present invention allow relatively easy retrieval while minimizing (if not preventing entirely) harm to the vascular endothelium.

While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiment, it is to be understood that the invention is not to be limited to the disclosed embodiment, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.



- 15 -

**WHAT IS CLAIMED IS:**

1. A blood filter sized and configured to be positioned within a vascular vessel comprising a plurality of anchoring arms for temporarily anchoring the blood filter to a wall of the vascular vessel, wherein said anchoring arms include an inner anchoring arm and an outer sleeve removably covering a portion of said inner anchoring arm.
2. The filter of claim 1, wherein said outer sleeve comprises a bioabsorbable polymeric material.
3. The filter of claim 2, wherein said sleeve comprises a length of monofilament formed of said bioabsorbable polymeric material wound around said portion of said inner anchoring arm.
4. The filter of claim 2, wherein said outer sleeve comprises a generally tubular element molded from said bioabsorbable polymeric material.
5. A vascular filter comprising a proximal support portion having a plurality of circumferentially spaced-apart anchoring arms which include a portion formed of a bioabsorbable polymeric material.
6. The filter of claim 5, wherein the anchoring arms comprise an inner anchoring arm and a removable sleeve formed of said bioabsorbable polymeric material covering said inner anchoring arm.

- 16 -

7. The filter of claim 6, wherein said sleeve is a length of monofilament formed of said bioabsorbable polymeric material which is wrapped around said portion of said inner anchoring arm..

8. The filter of claim 6, wherein said sleeve includes a tubular element molded from said bioabsorbable polymeric material.

9. The filter of claim 2 or 6, wherein said bioabsorbable polymeric material is a hydrolyzable polymer.

10. The filter of claim 1 or 6, wherein said inner anchoring arm has a generally round or rectangular cross-section.

11. The filter of claim 1 or 6, wherein said inner anchoring arm has a longitudinal split.

12. The filter of claim 1 or 6, wherein said inner anchoring arm has a generally helical configuration.

13. The filter of claim 1 or 5, further comprising a distal filter portion.

14. The filter of claim 13, wherein said distal filter portion comprises a plurality of distally divergent filter arms.

15. The filter of claim 14, wherein at least some of said filter arms are inferiorly curved.

- 17 -

16. The filter of claim 14, wherein at least some of said filter arms are formed of elongate loops.

17. The filter of claim 14, wherein at least some of said filter arms include a distal loop.

18. The filter of claim 2 or 6, which comprises:

a distal filter portion which includes a plurality of distally divergent filter arms; and

a support portion proximally disposed and connected to said filter portion, wherein said support portion includes a plurality of distal and proximal support arms connected at respective intermediate junctures; wherein

said inner anchoring arms extend from respective ones of said intermediate junctures of said distal and proximal support arms.

19. The filter of claim 18, further comprising a plurality of extension arms which join respective ones of said inner anchoring arms and said intermediate junctures.

20. The filter of claim 19, wherein said sleeve comprises a length of monofilament formed of said bioabsorbable polymeric material wound around said portion of said inner anchoring arm.

21. The filter of claim 19, wherein said outer sleeve comprises a generally tubular element molded from said bioabsorbable polymeric material.

- 18 -

22. The filter of claim 18, wherein said sleeve comprises a length of monofilament formed of said bioabsorbable polymeric material wound around said portion of said inner anchoring arm.

23. The filter of claim 18, wherein said outer sleeve comprises a generally tubular element molded from said bioabsorbable polymeric material.

24. A blood vessel filter, comprising:

- a collapsible body, said collapsible body being collapsible toward a longitudinal axis for insertion into a blood vessel and being expandable for anchoring said blood vessel filter to a wall of said blood vessel, said collapsible body having proximal and distal ends;

- a filter portion attached to said collapsible body at said distal end;

- a plurality of spaced inner anchoring arms extending from said collapsible body, said anchoring arms contacting said wall of said blood vessel when said collapsible body is expanded; and

- a plurality of removable sleeves fitted over said anchoring arms; wherein

- said sleeves are detachable from said anchoring arms during removal of said collapsible body from said blood vessel.

25. The filter of claim 24, which comprises:

- said filter portion includes a plurality of distally divergent filter arms; and wherein

- said filter comprises a support portion proximally disposed and connected to said filter portion, wherein said support portion includes

- 19 -

a plurality of distal and proximal support arms connected at respective intermediate junctures; wherein

said inner anchoring arms extend from respective ones of said intermediate junctures of said distal and proximal support arms.

26. The filter of claim 25, further comprising a plurality of extension arms which join respective ones of said inner anchoring arms and said intermediate junctures.

27. The filter of claim 24, 25 or 26, wherein said sleeve comprises a length of monofilament formed of said bioabsorbable polymeric material wound around said portion of said inner anchoring arm.

28. The filter of claim 24, 25 or 26, wherein said outer sleeve comprises a generally tubular element molded from said bioabsorbable polymeric material.

29. The filter of claim 24, 25 or 26 wherein said sleeve is formed of a hydrolyzable polymeric material.

30. A method of making a temporary vascular filter having a circumferentially spaced apart plurality of anchoring arms, which comprises forming a removable sleeve over said anchoring arms.

31. The filter of claim 30, which comprises forming the removable sleeve from a bioabsorbable polymeric material.

32. The method of claim 31, wherein said step of forming a removable sleeve comprises covering at least a portion of said anchoring

- 20 -

arms by wrapping a monofilament of said bioabsorbable polymeric material therearound.

33. The method of claim 31, wherein said step of forming a removable sleeve comprises molding a tubular element over said anchoring arms.

34. The method of any one of claims 30-33, further comprising forming a distal filter portion by attaching a distally divergent plurality of filter arms to a proximal support structure which includes said anchoring arms

1/26

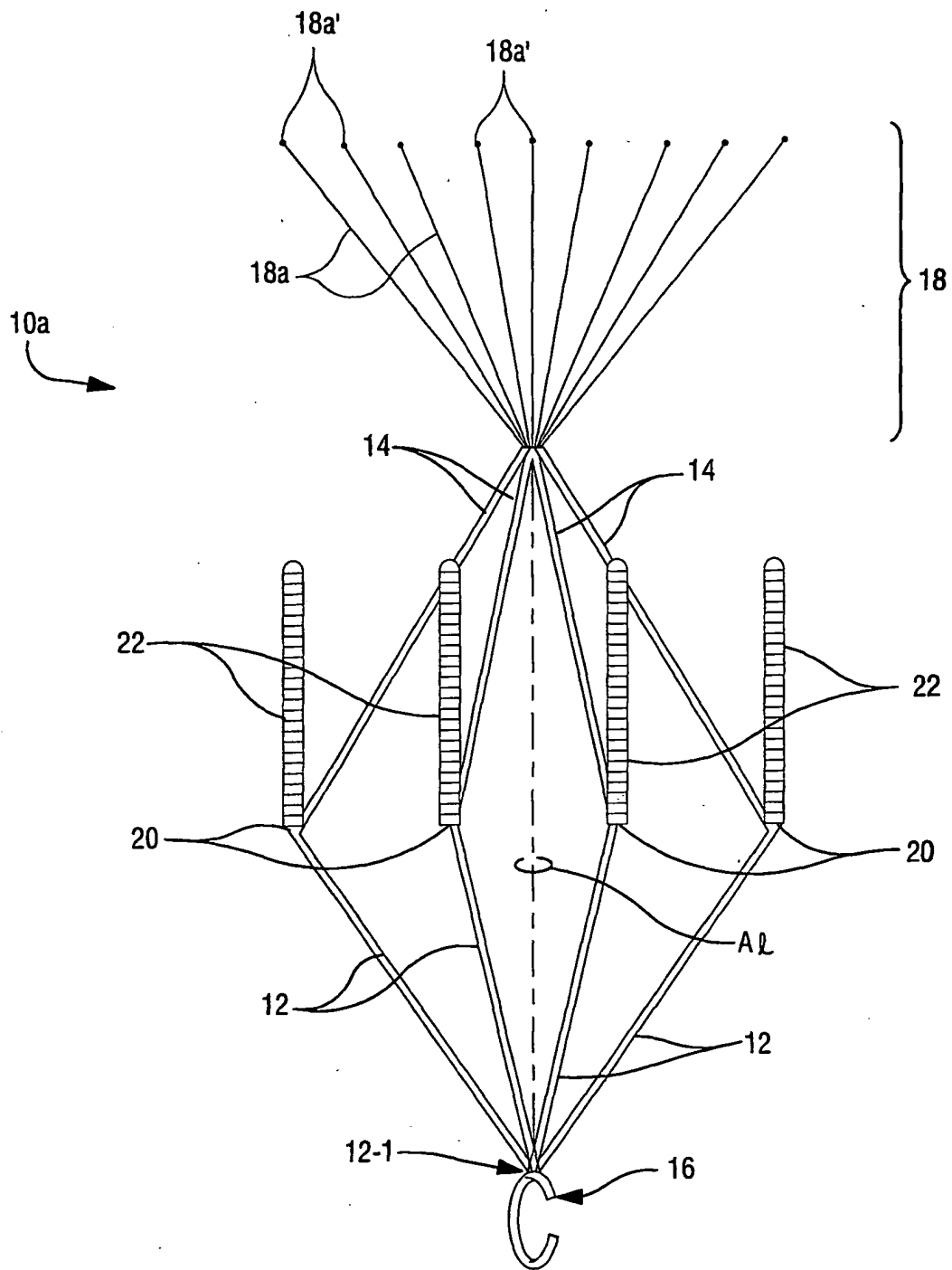


Fig. 1A

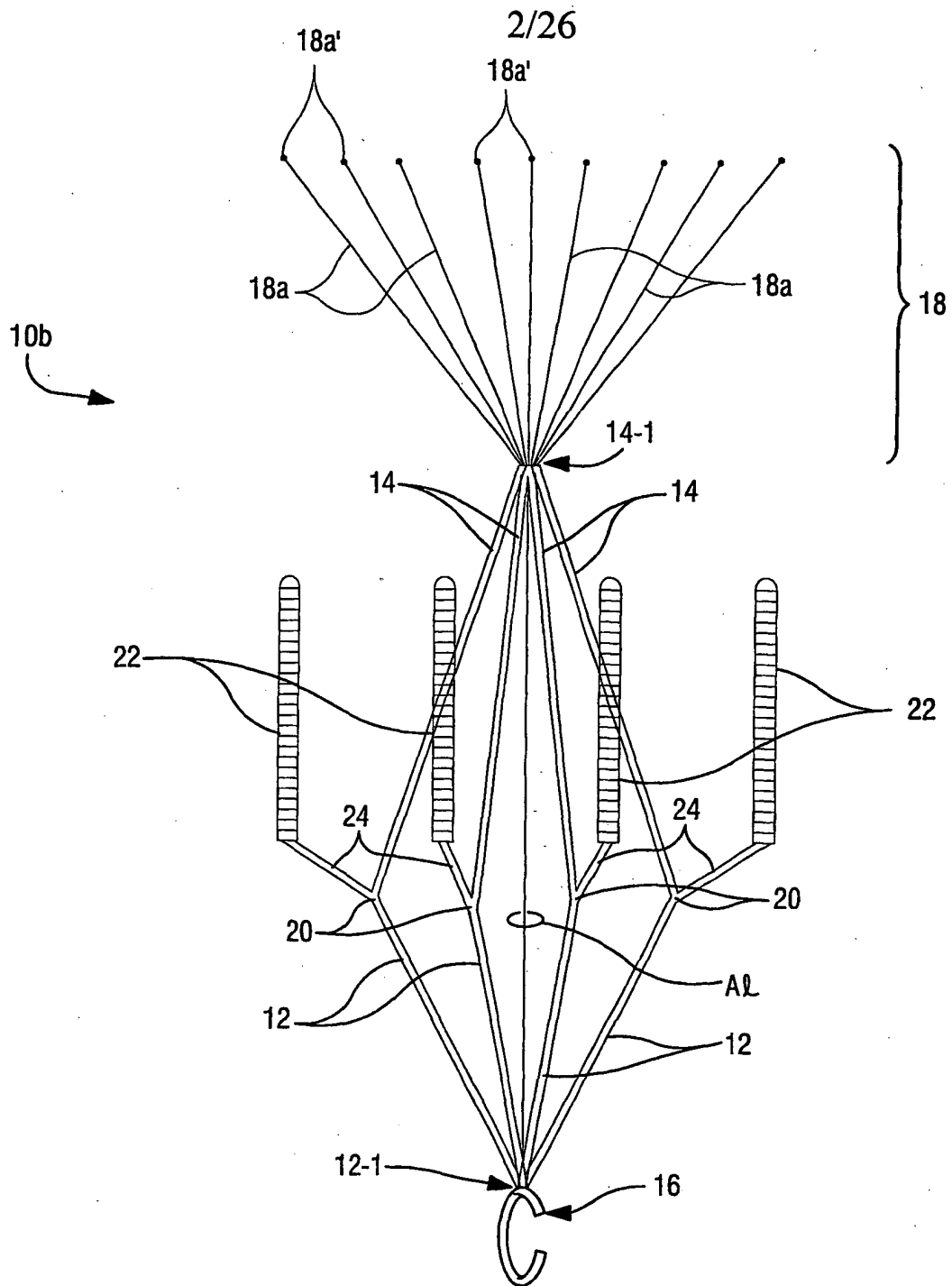


Fig. 1B



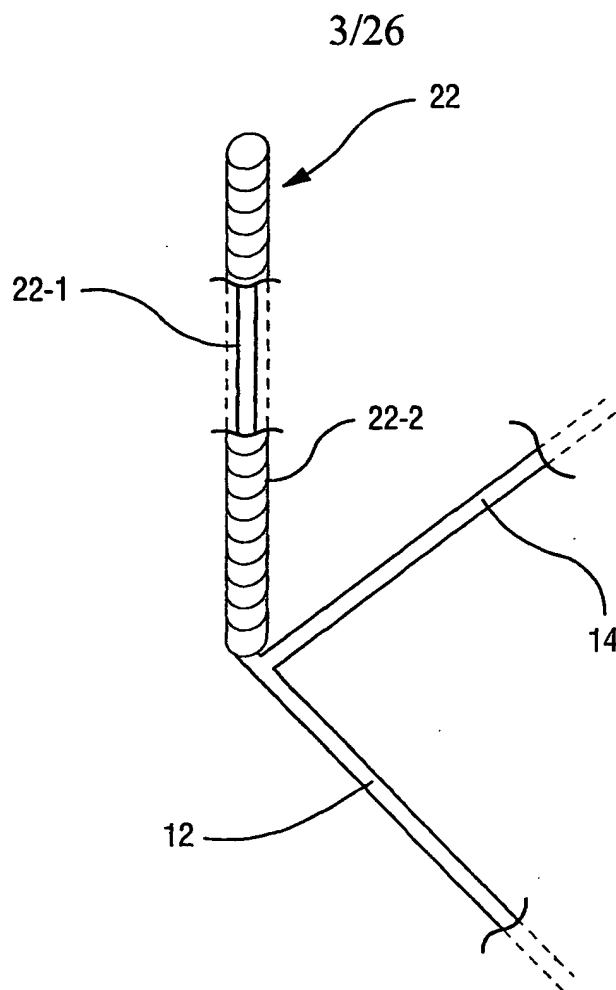


Fig. 2A

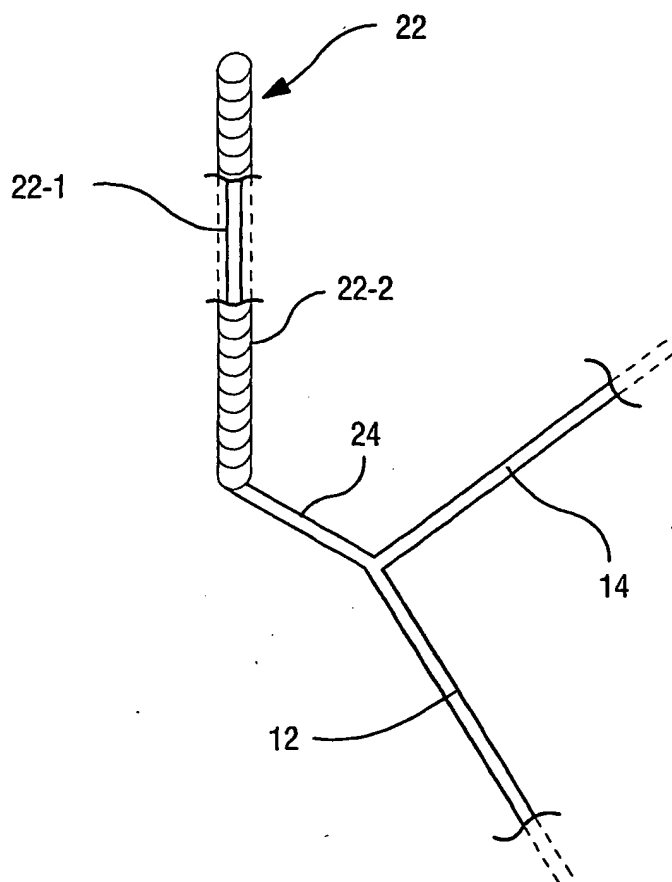


Fig. 2B

4/26

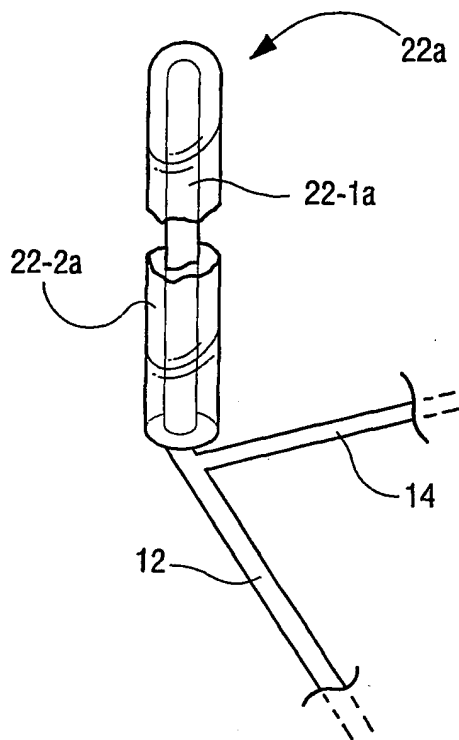


Fig. 3A

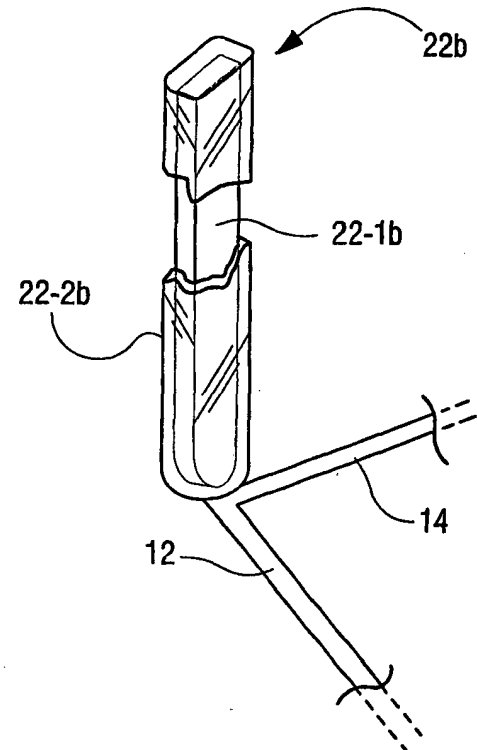


Fig. 3B

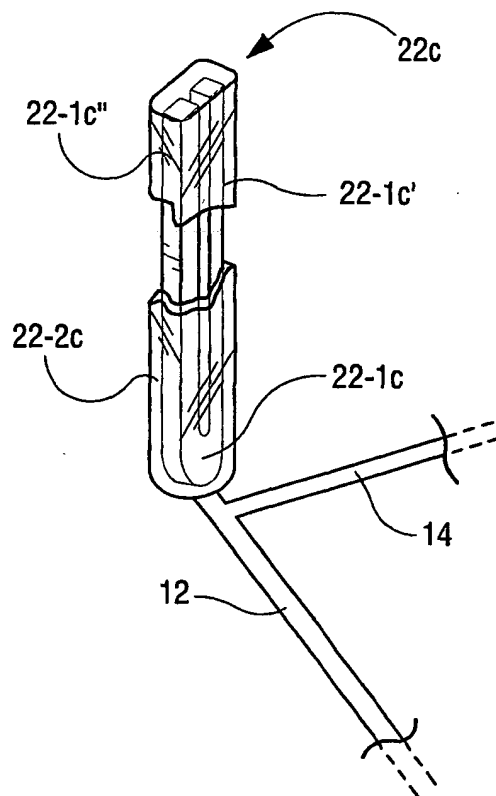


Fig. 3C

5/26

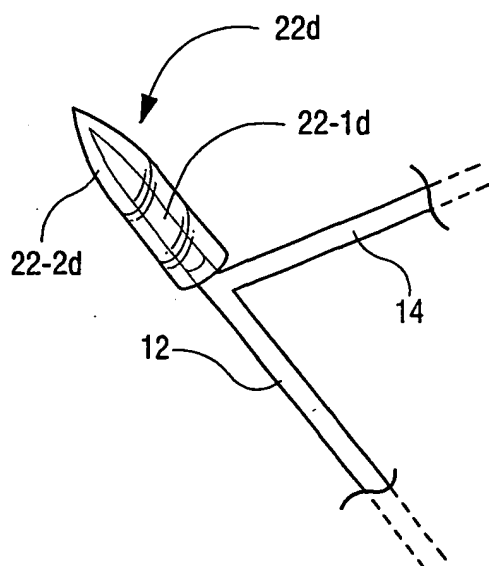


Fig. 3D

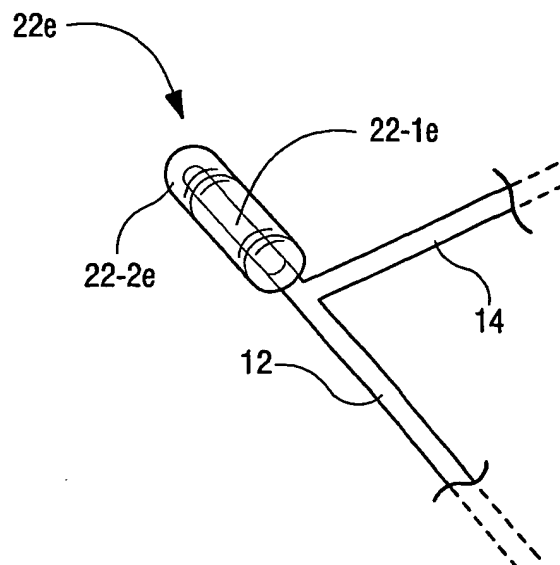


Fig. 3E

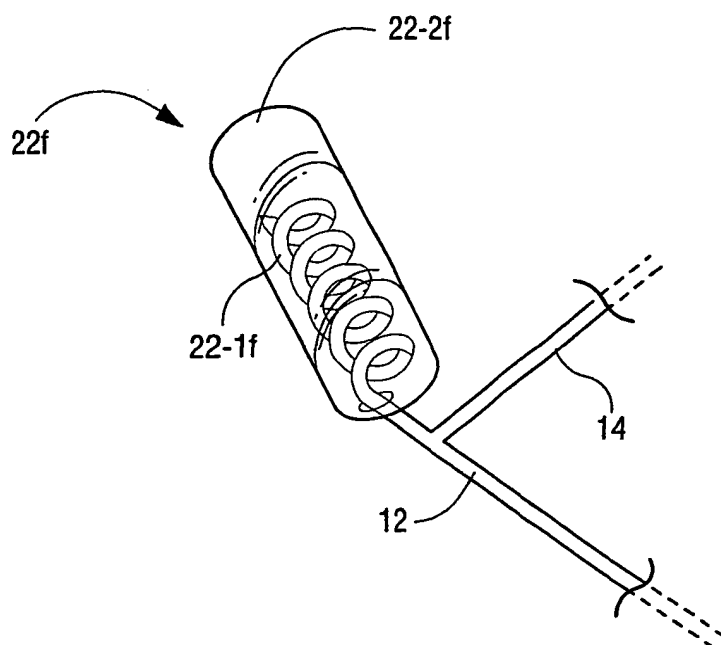


Fig. 3F

6/26

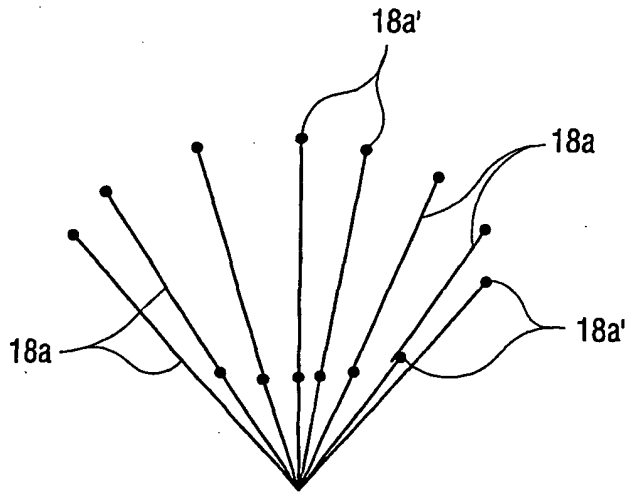


Fig. 4A

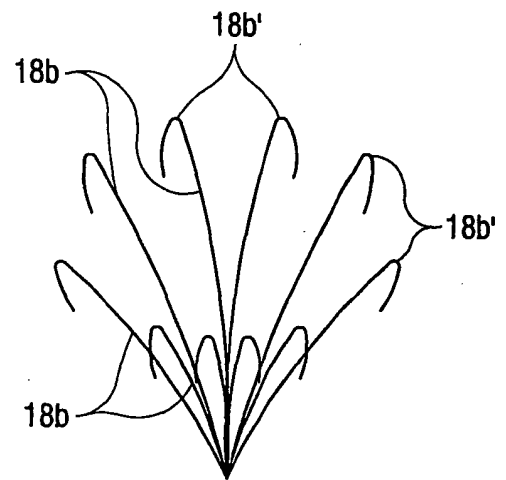


Fig. 4B

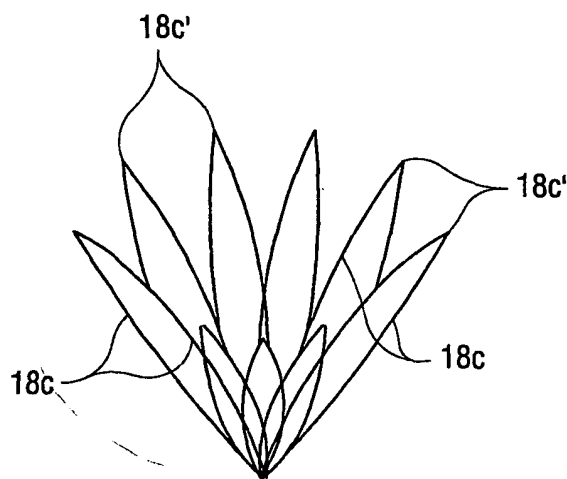


Fig. 4C

7/26

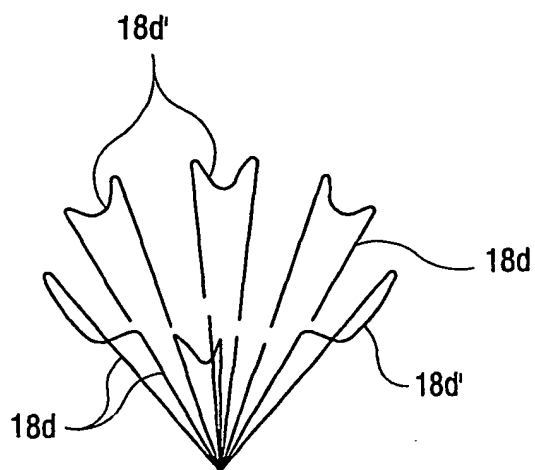


Fig. 4D

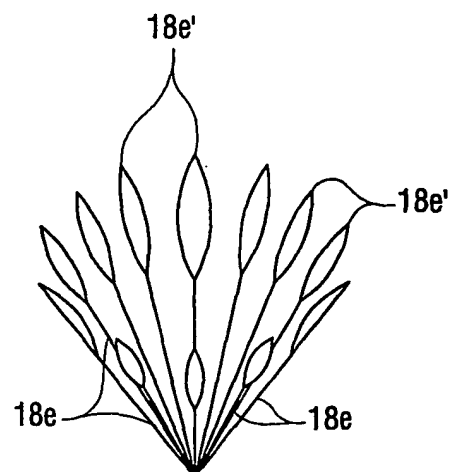


Fig. 4E

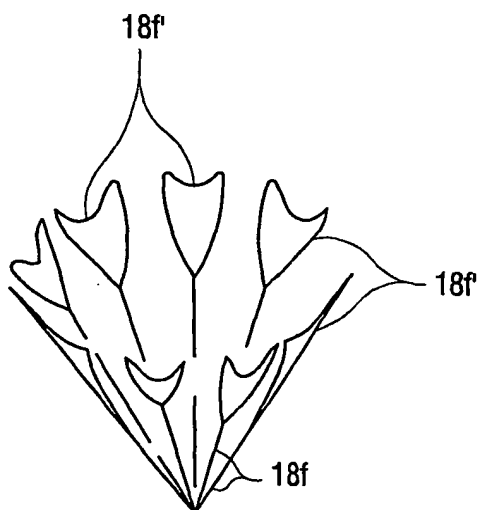


Fig. 4F

8/26

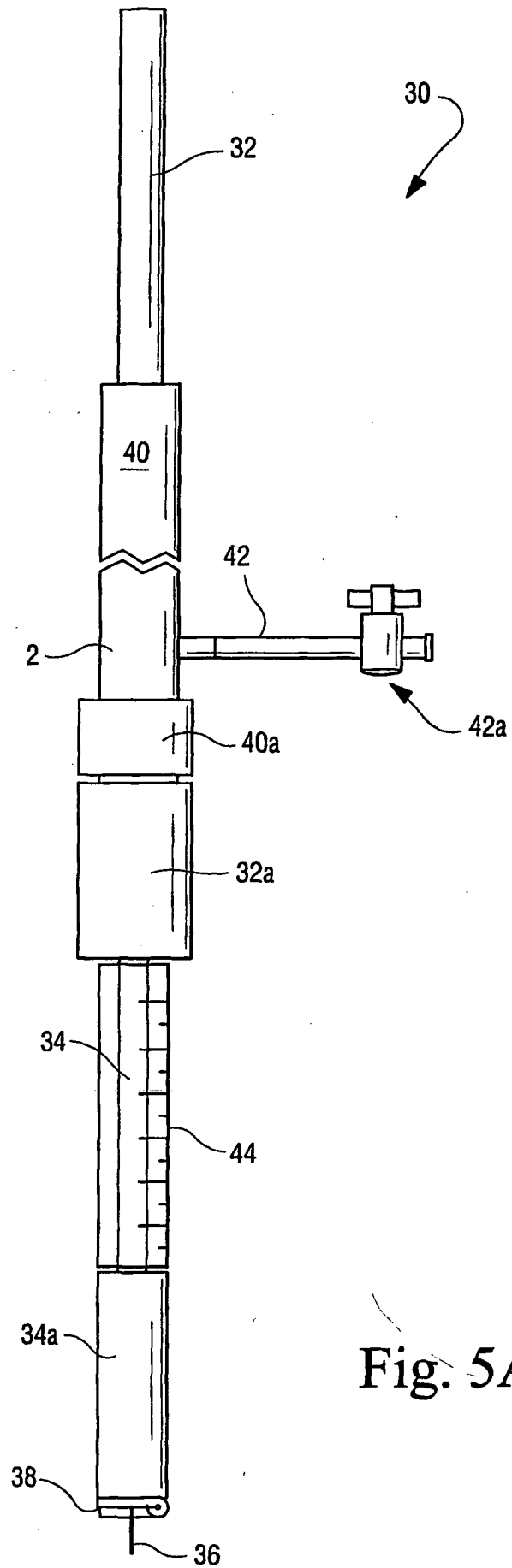


Fig. 5A

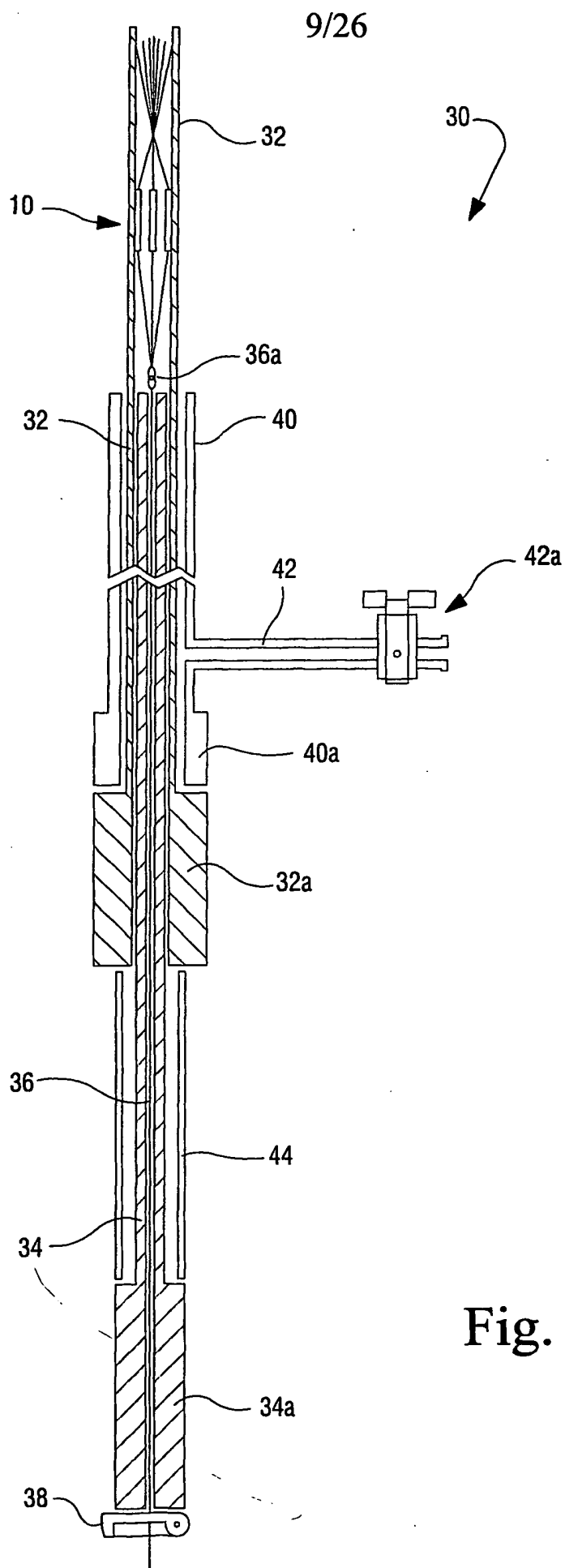


Fig. 5B

10/26

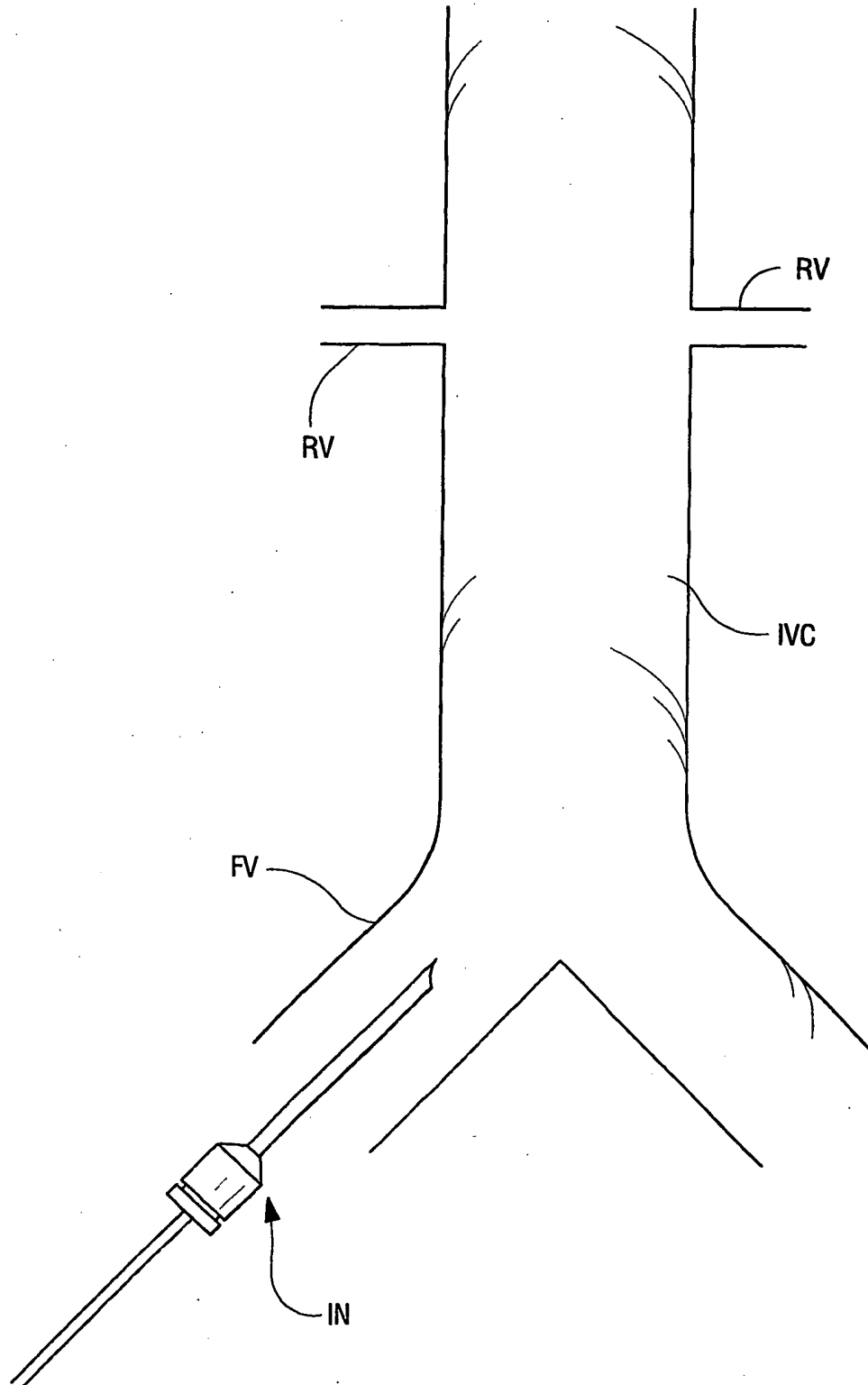


Fig. 6A



11/26

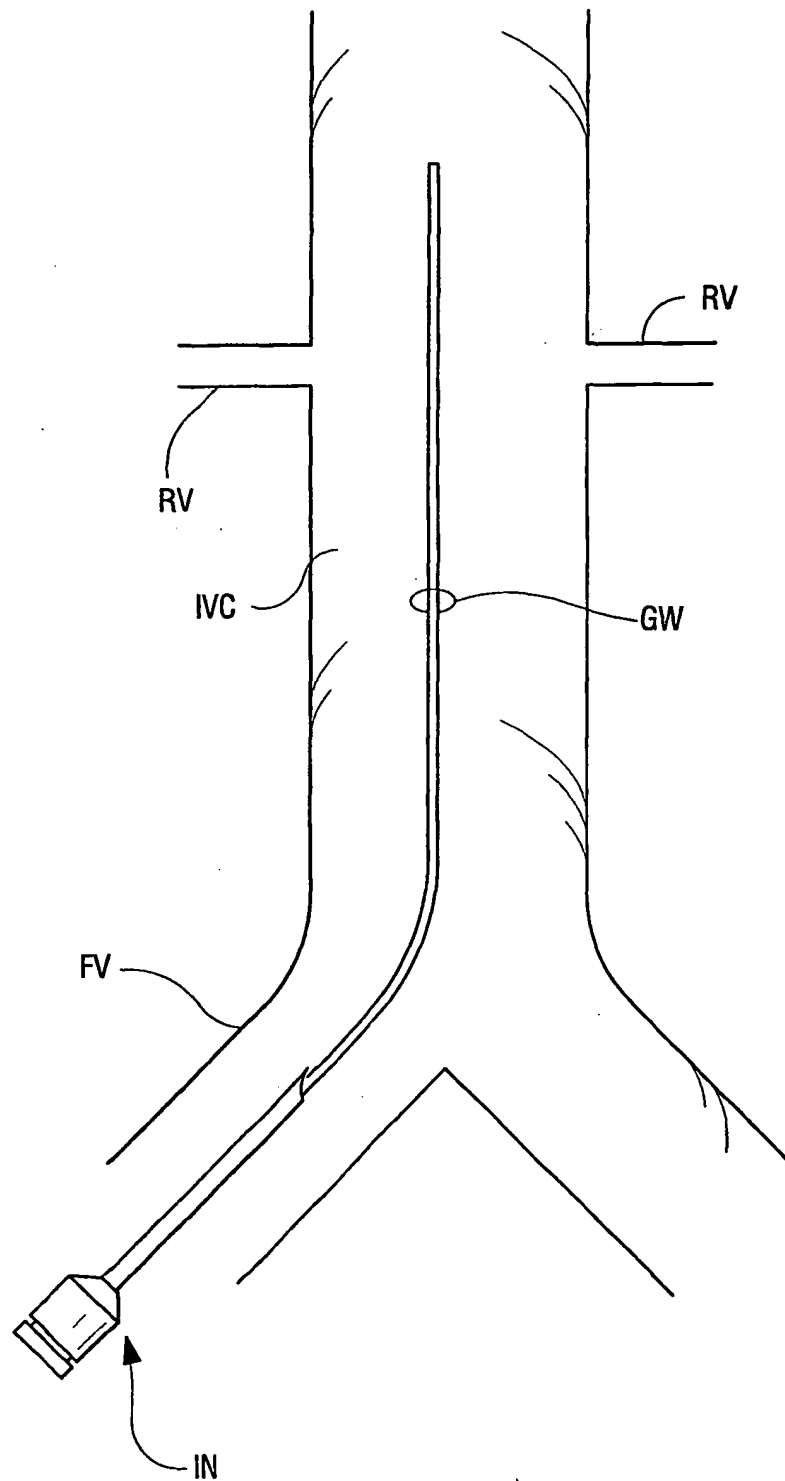


Fig. 6B

12/26

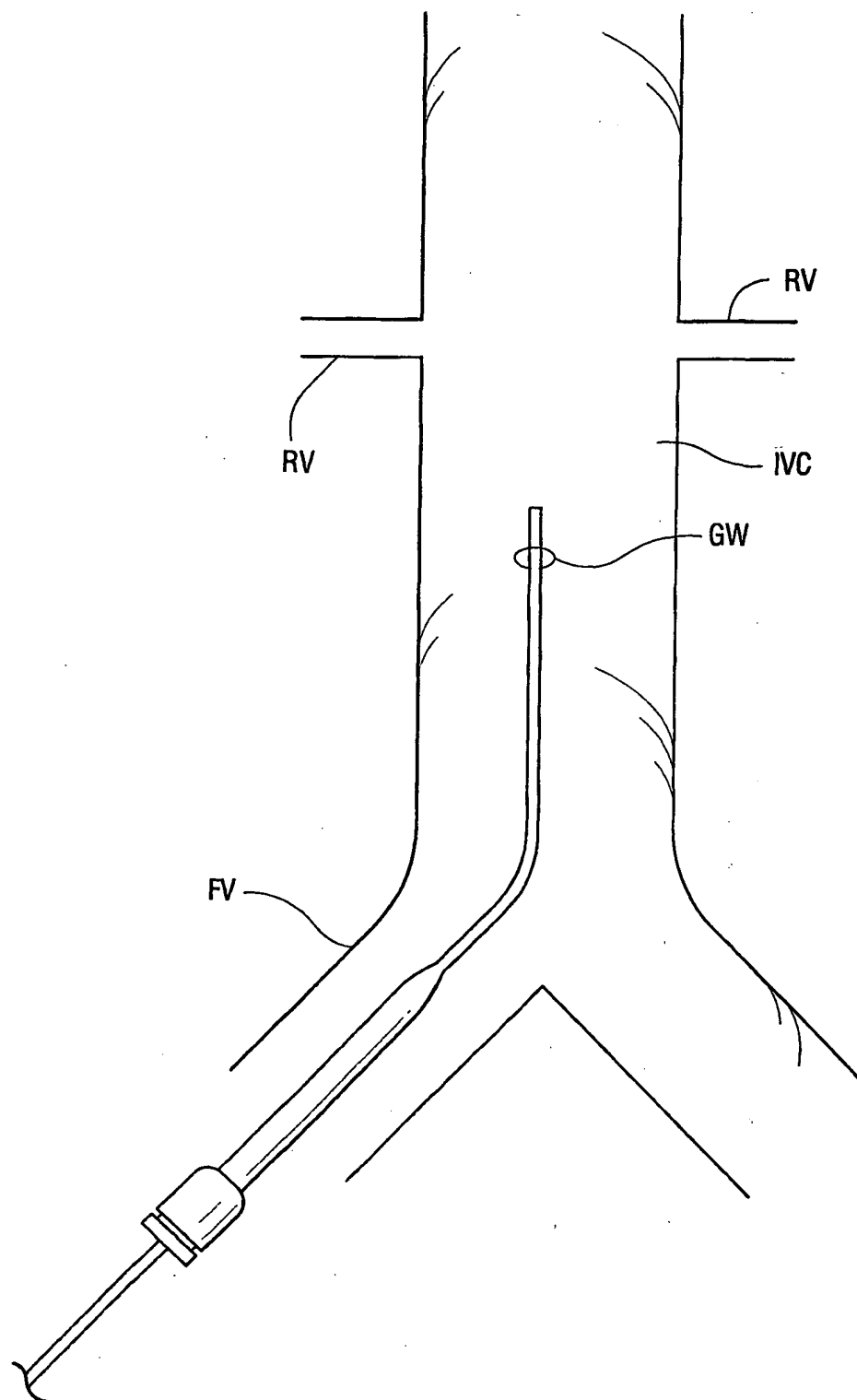


Fig. 6C

13/26

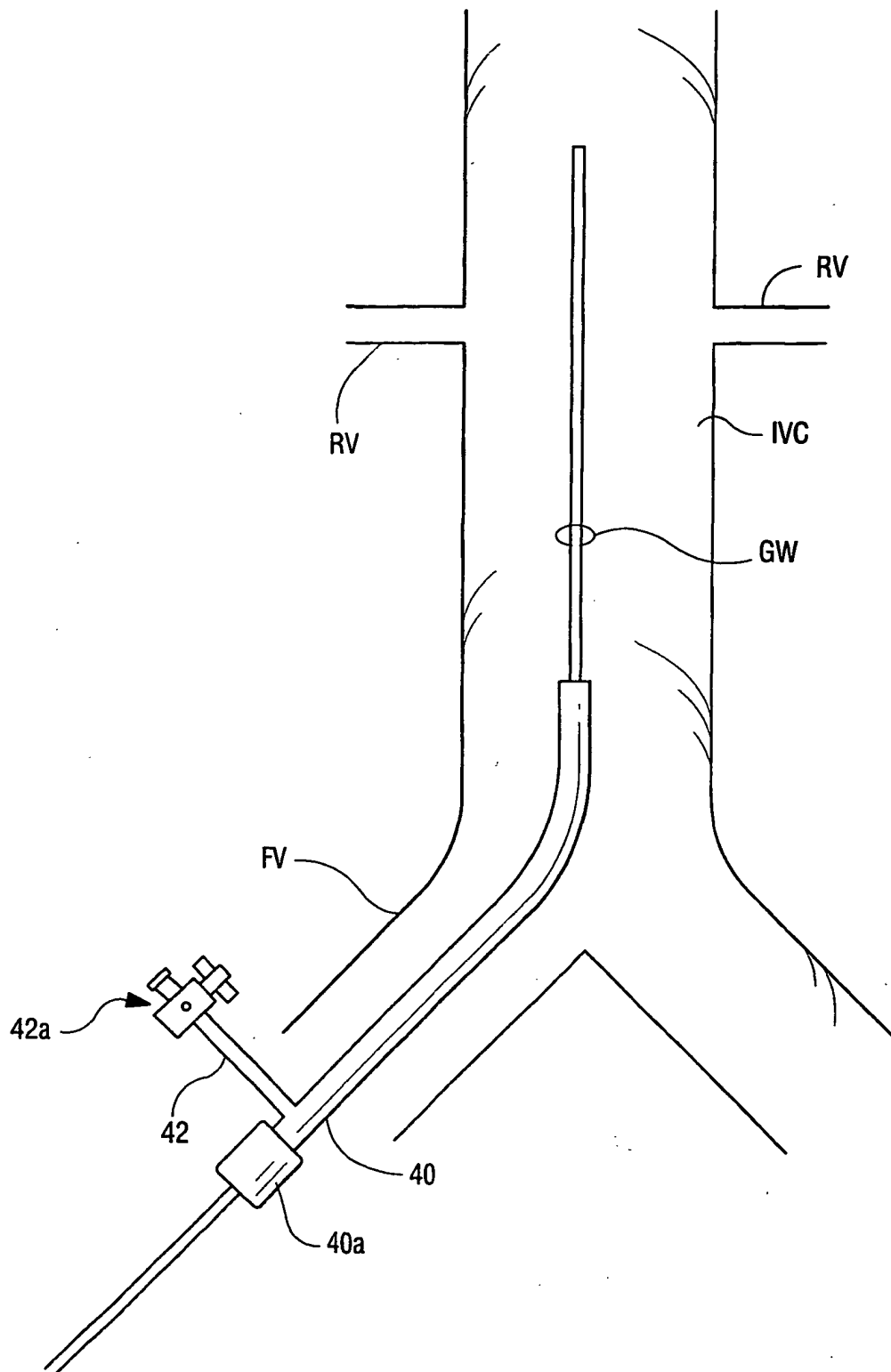


Fig. 6D

14/26

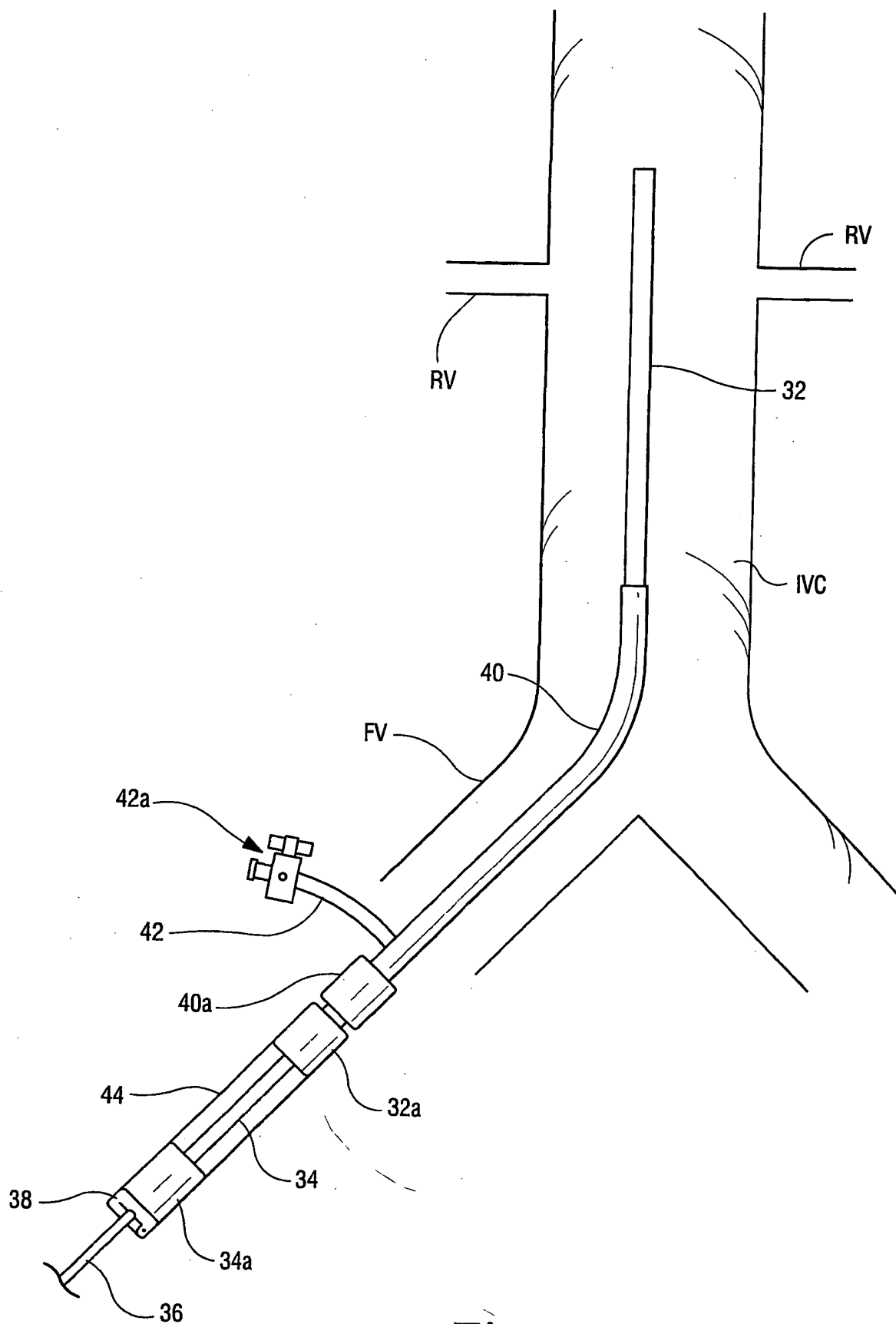


Fig. 6E

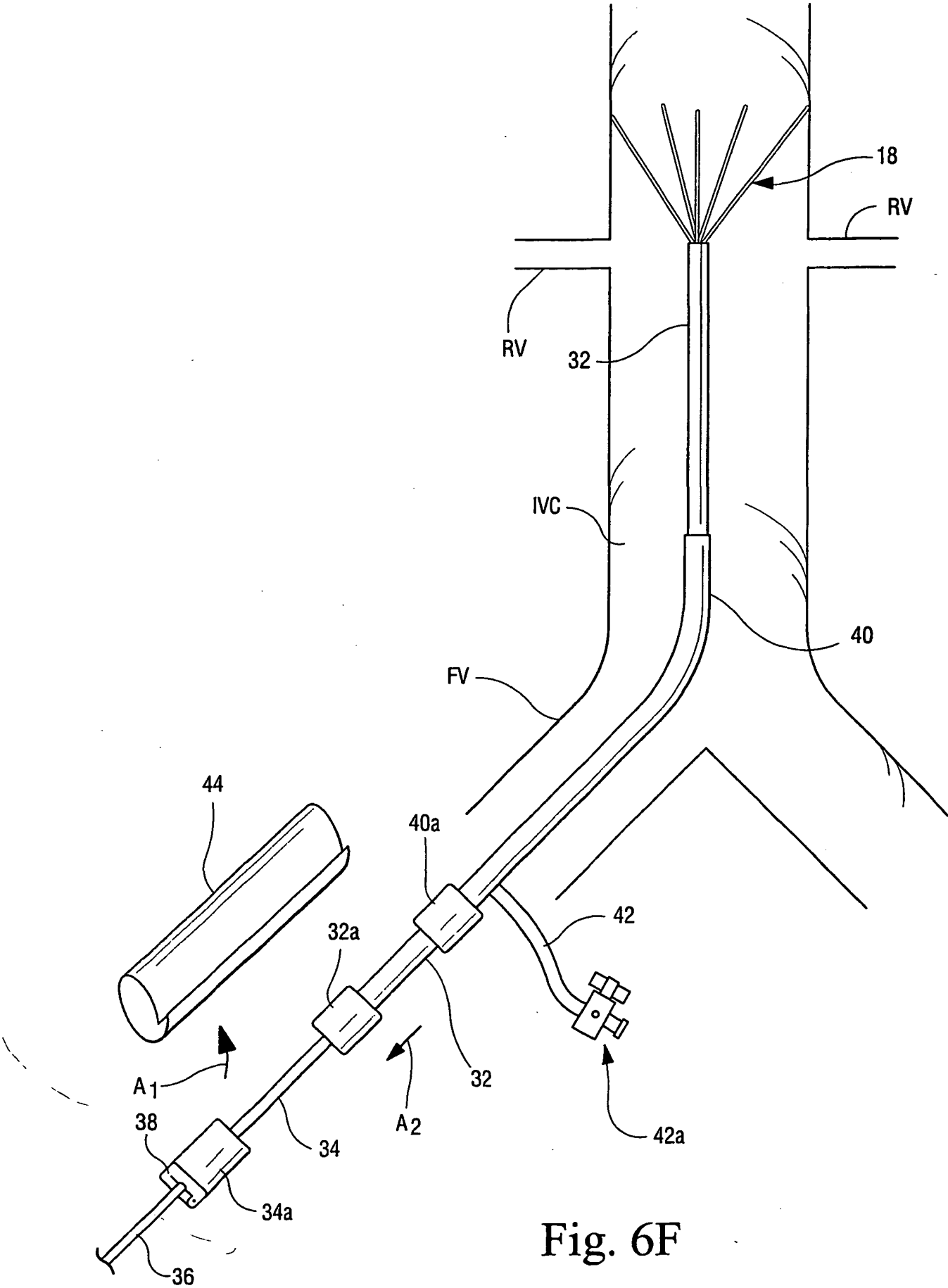


Fig. 6F

16/26

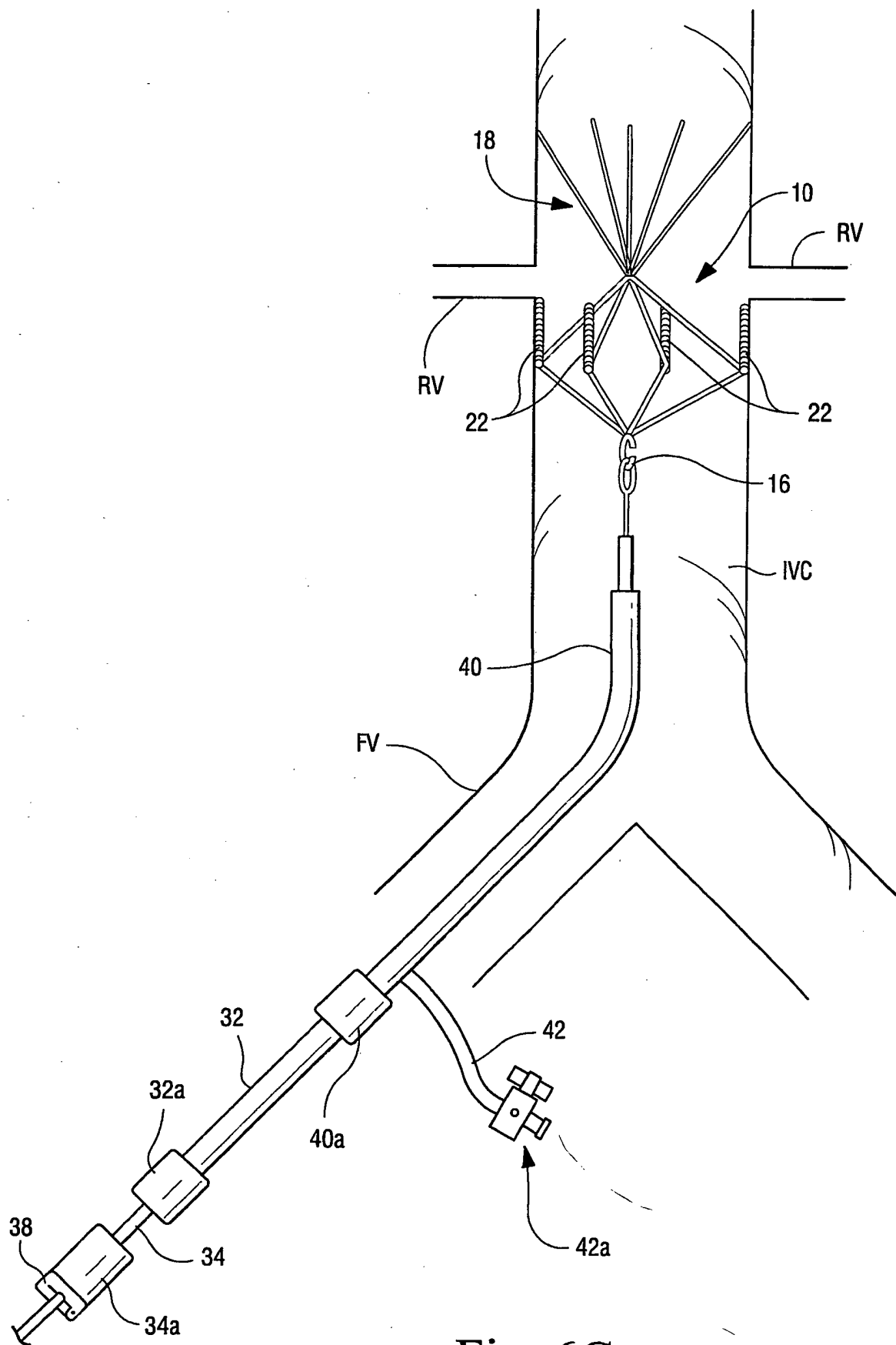
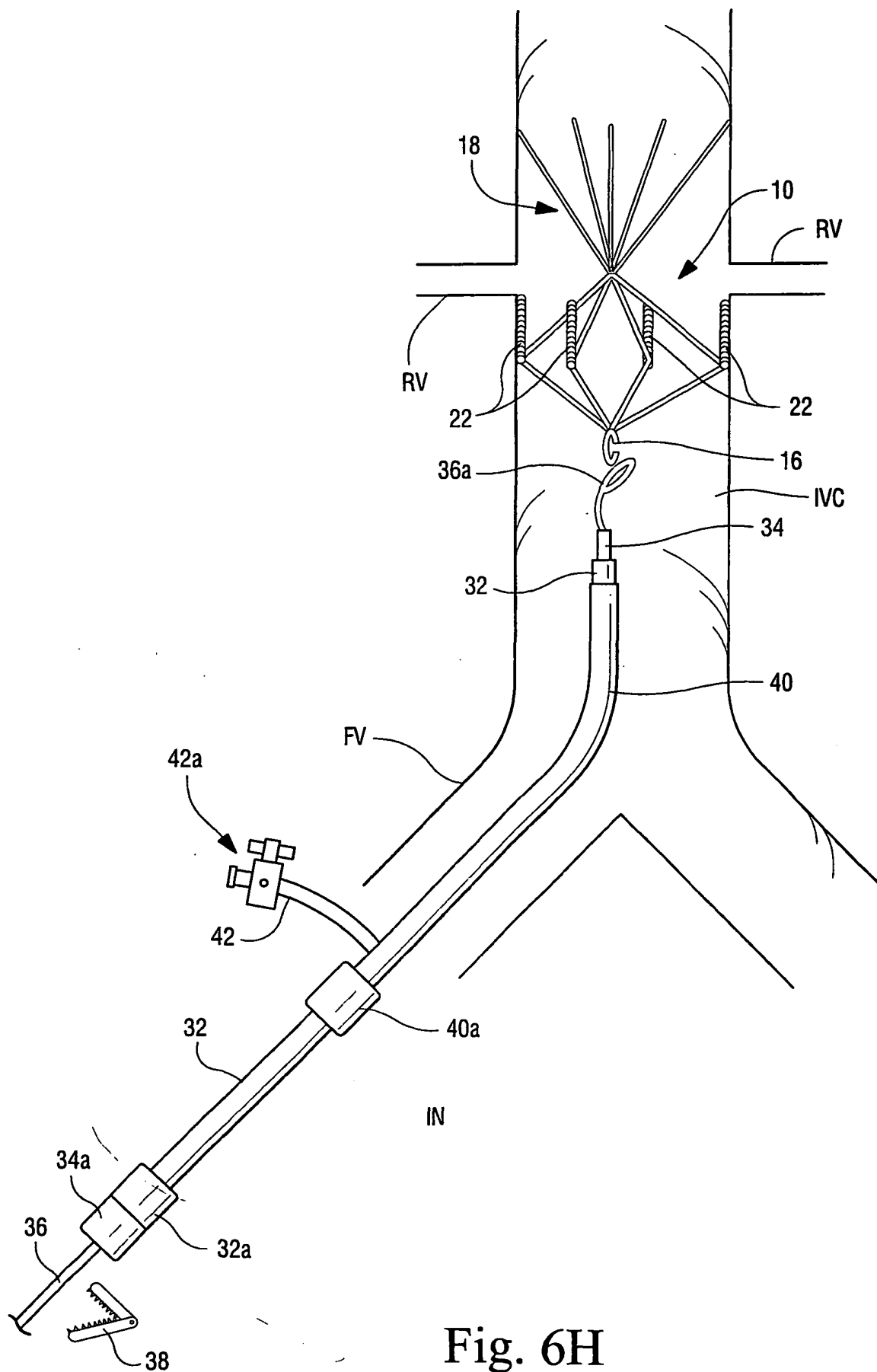


Fig. 6G

17/26



18/26

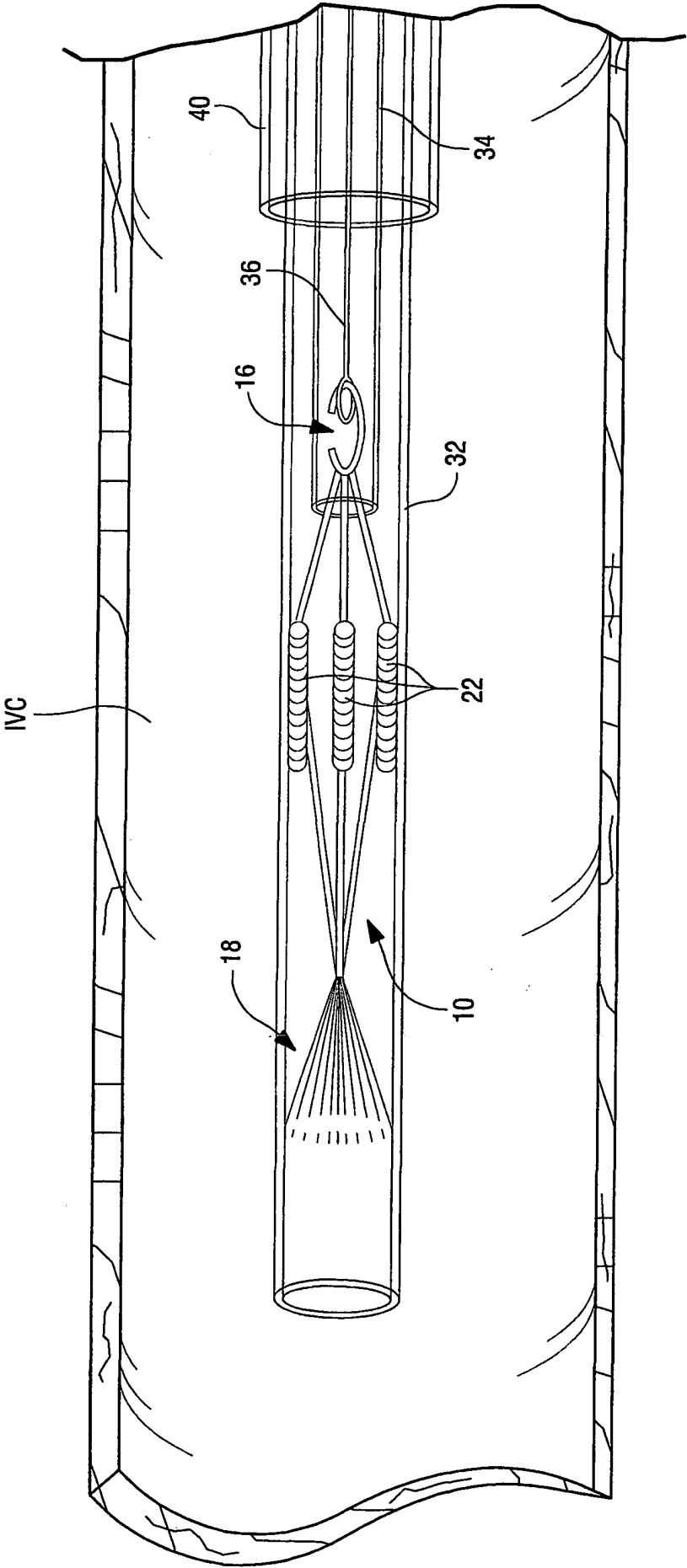


Fig. 7A



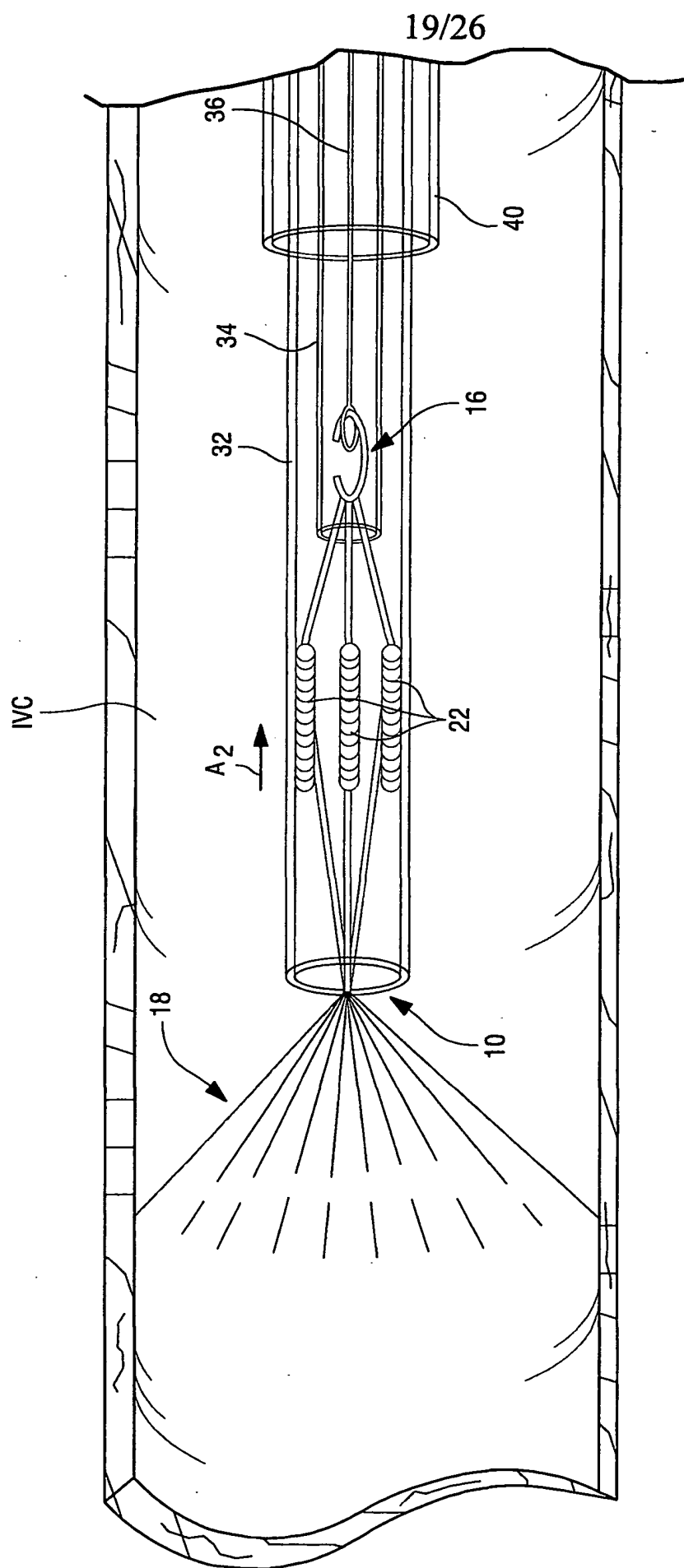


Fig. 7B

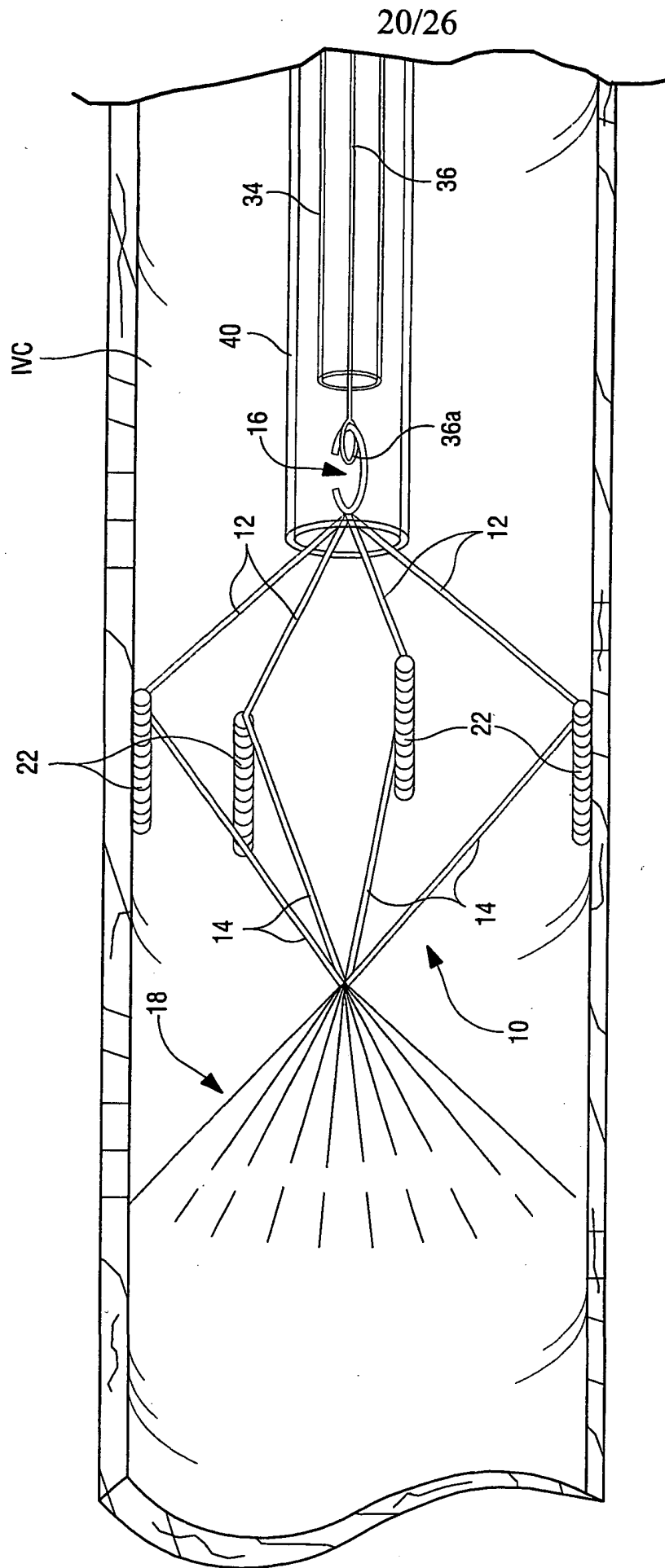


Fig. 7C

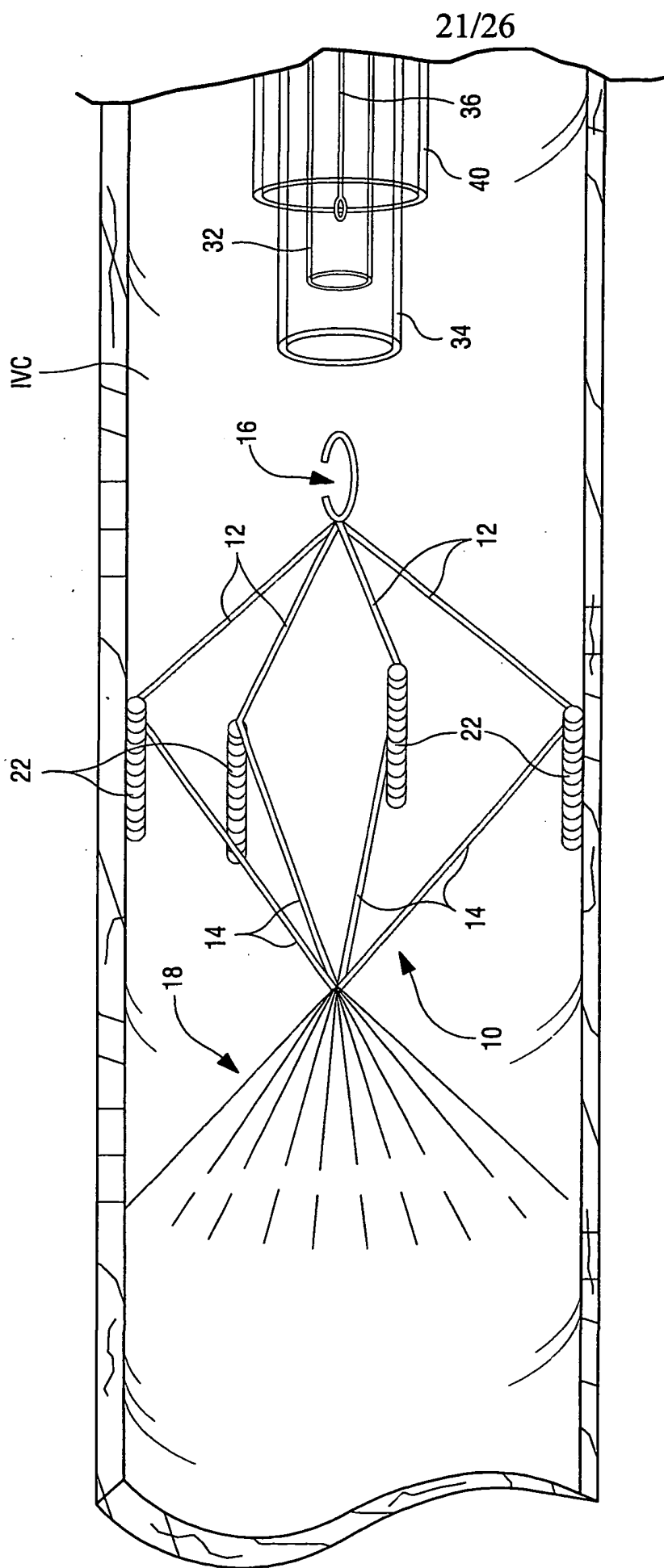


Fig. 7D

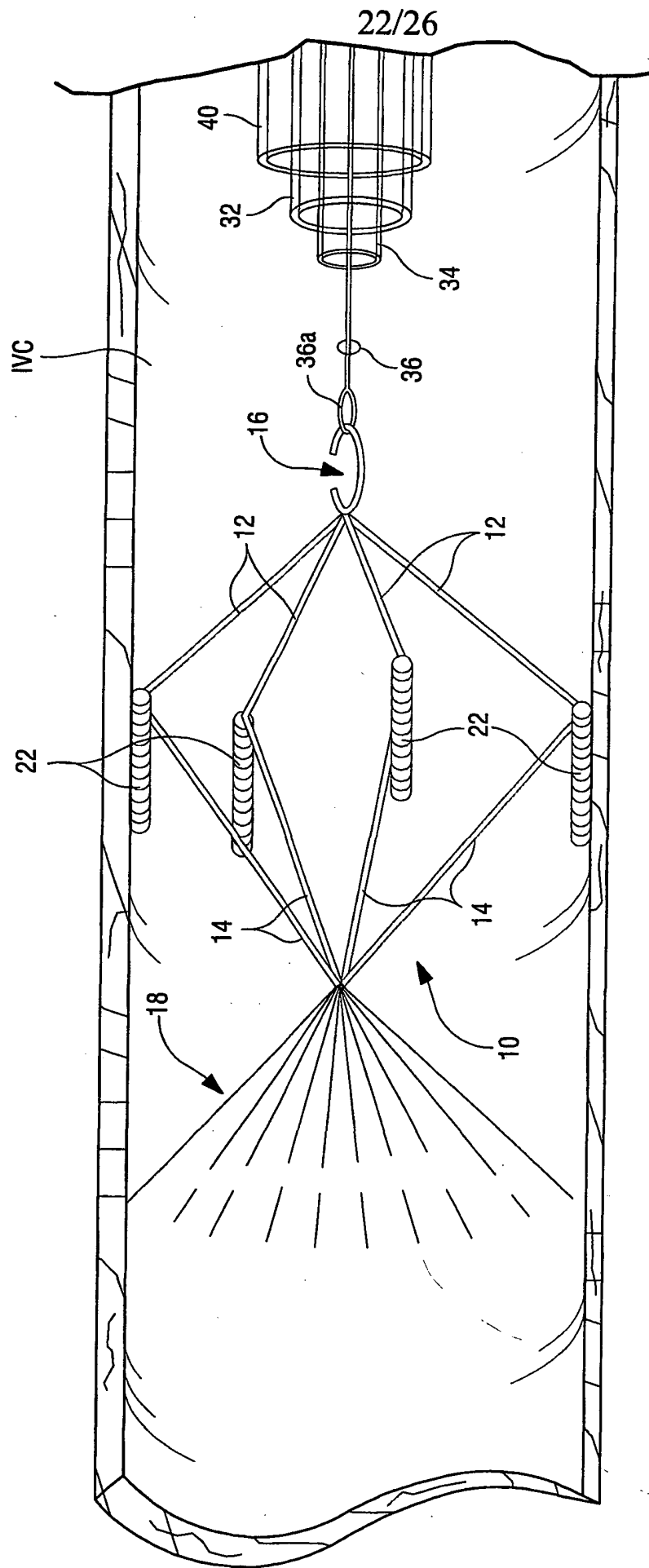


Fig. 8A

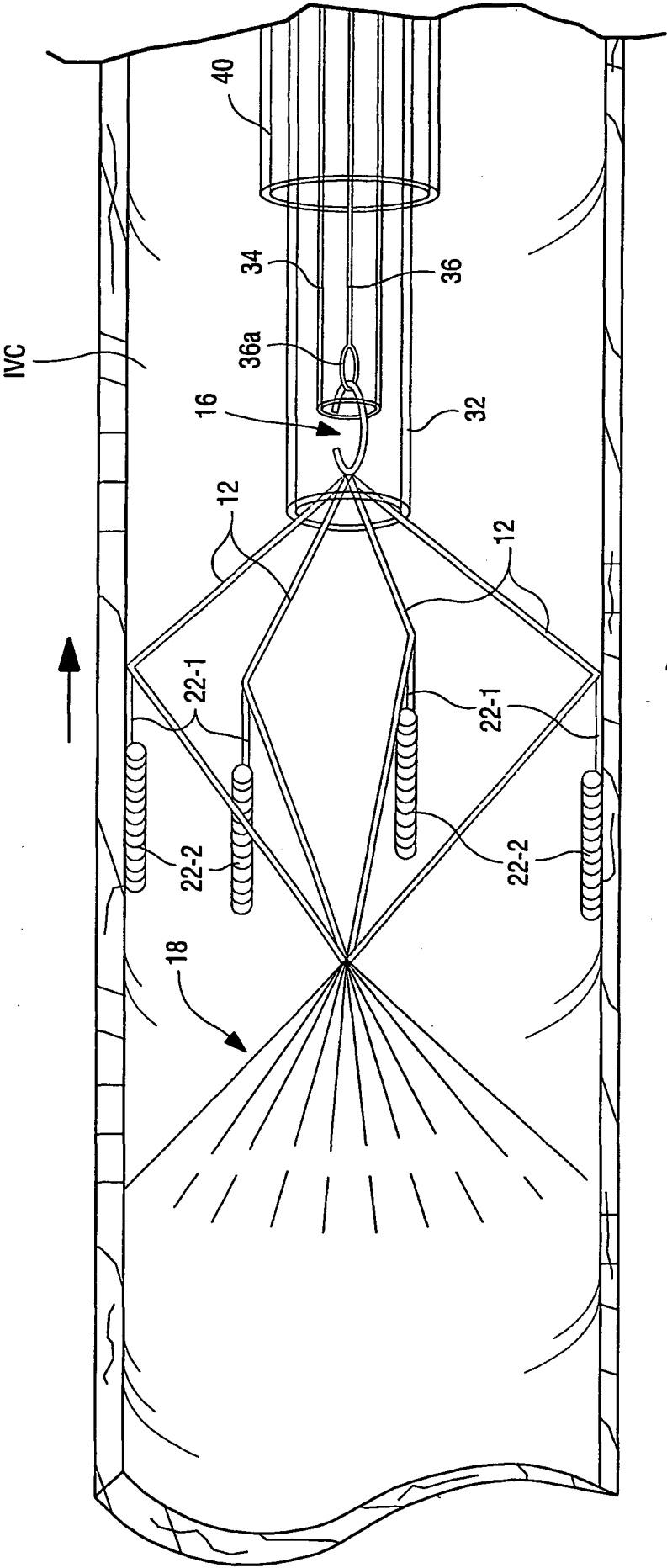


Fig. 8B

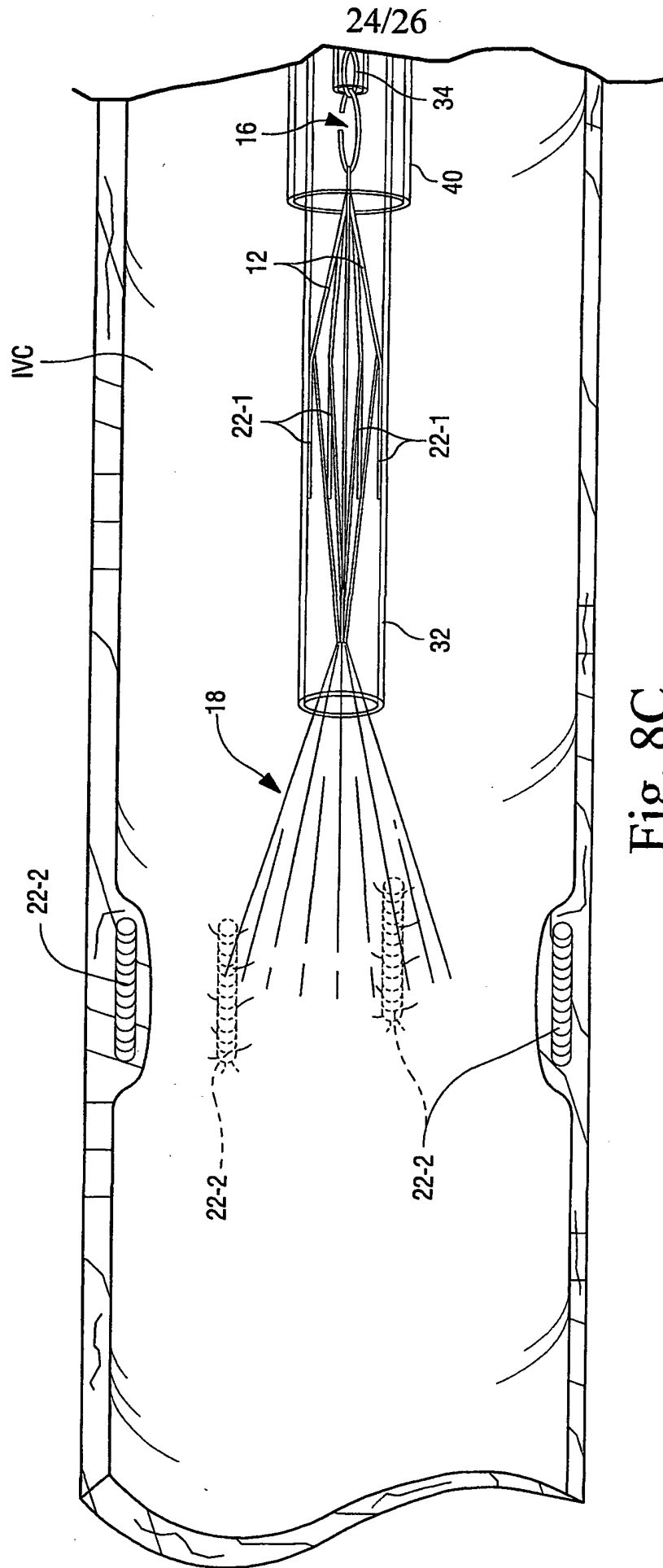


Fig. 8C

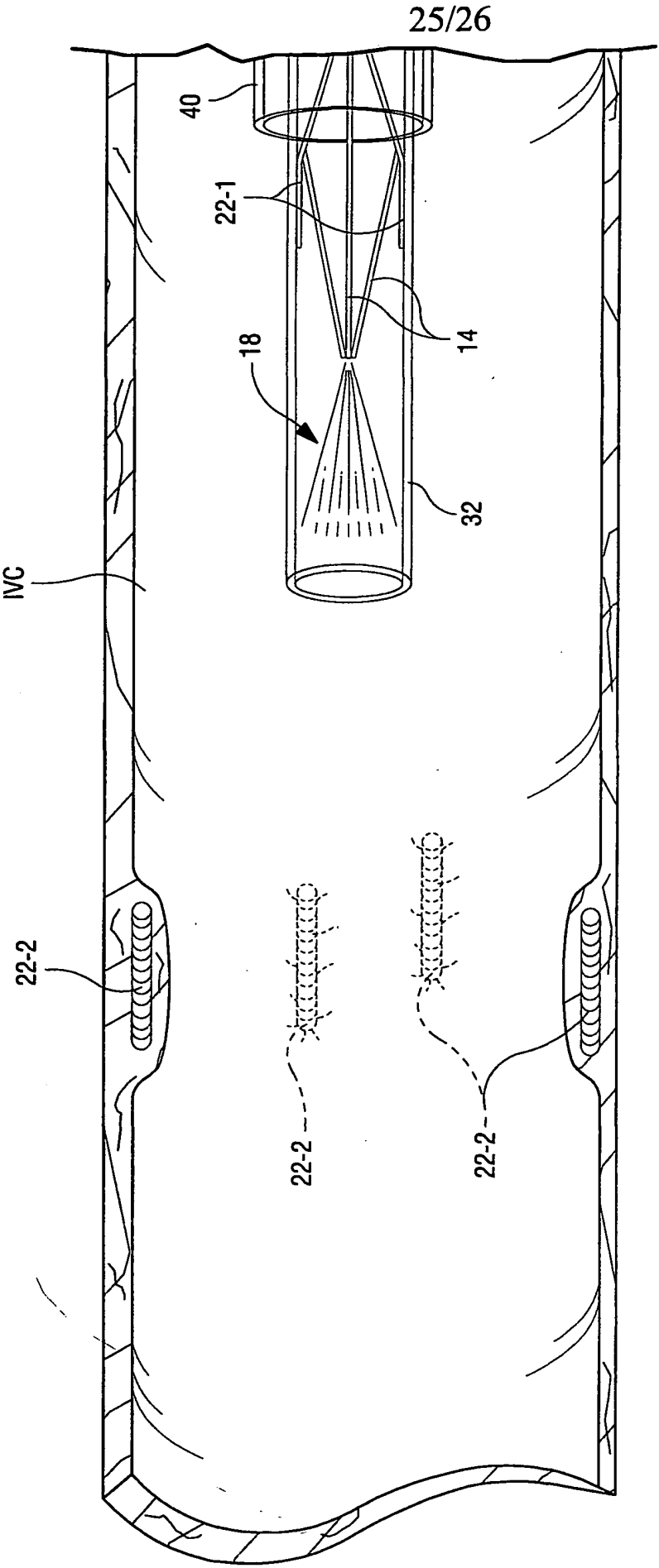


Fig. 8D

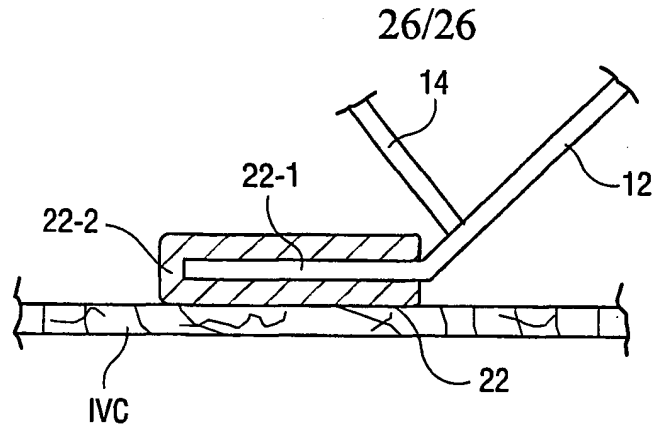


Fig. 9A

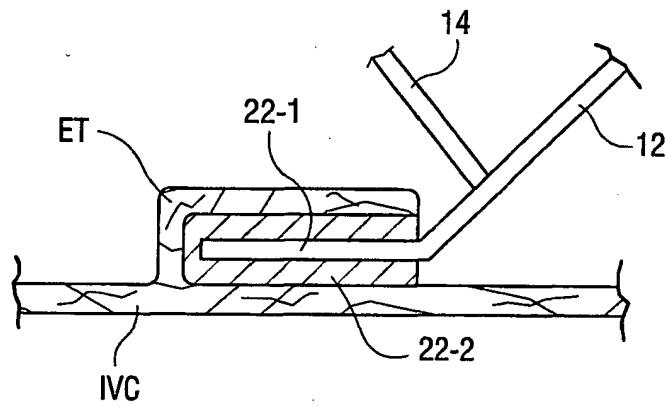


Fig. 9B

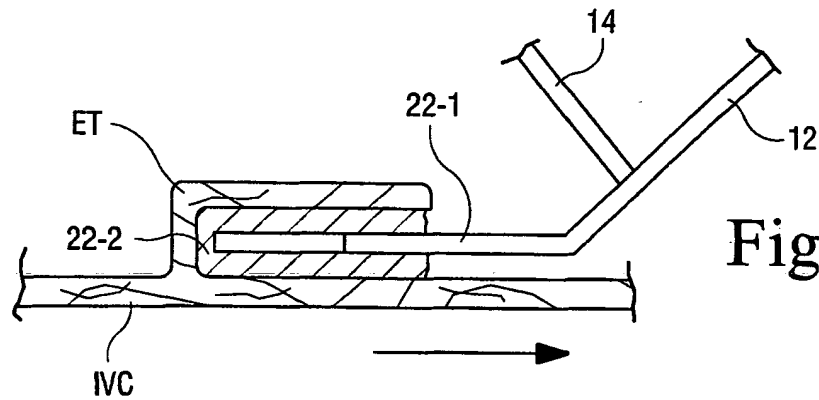


Fig. 9C

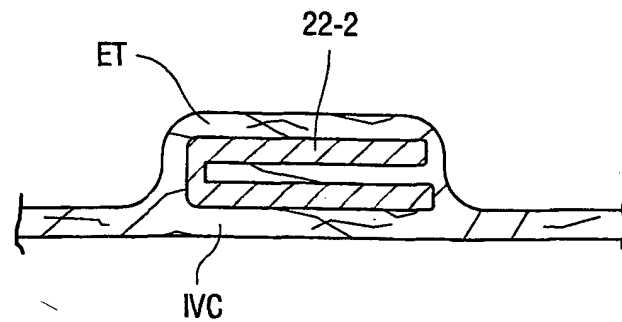


Fig. 9D



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/23868

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : AG1M 29/00

US CL : 606/200, 191, 194, 198

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/200, 191, 194, 198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X. E	WO01/54617 A1 (DEVRIES et al) 02 AUGUST 2001; Figs. 1 and 3.	1, 10, 13, 22, 30.

BEST AVAILABLE COPY

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

06 NOVEMBER 2001

Date of mailing of the international search report

03 JAN 2002

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

Henry Recla

Telephone No. (703) 306-3420



***This Page Blank (uspto)***